Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 1/14/2020 2:56:20 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Aldicarb - Revisions (with and with out comments)
Attachments: Aldicarb Citrus New Use Summary Paperm 1.14.20 dnr No Comments.docx; Aldicarb Citrus New Use Summary Paperm 1.14.20 dnr.docx

Hi Marion,

Here is the latest version with and without comments. Let me know what you think.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Aldicarb Proposed Use on Citrus Issue Paper
DRAFT January 14, 2020

Issue

AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. OPP met with the registrant to discuss the specific risk concerns with the proposed new uses for this active ingredient. Understanding the challenges, the registrant elected to make a submission on April 9, 2019. The PRIA due date for this action is July 15, 2020. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Regulatory History

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity, and to protect ground water.
- Aldicarb products are currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. There are no registered residential uses of aldicarb.
- In 2010, Bayer (the registrant at that time) voluntarily agreed to cancel the domestic aldicarb uses on citrus (and potatoes), due to the findings by EPA that the registered uses posed an unacceptable dietary risk, especially to infants and young children. However, the existing tolerances for citrus have been maintained to allow for treated imports. Further, the registrant adopted risk mitigation measures for the remaining uses to protect groundwater resources.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.
    - The EPA risk assessment for the 2017 ID depicted risk estimates for dietary (food only) exposure below the level of concern, which included citrus exposure from imported commodities only.
    - Drinking water risks were mitigated by appropriate well setbacks, based upon such factors such as location and soil type, and considering in-furrow applications were at a depth of the one inch or greater.

Current Submission

- To support the registration of aldicarb on citrus in Florida and Texas, AgLogic did not submit new data, but instead conducted their own dietary exposure and drinking water exposure assessments. The company asserts that these analyses demonstrate that there are no risks of concern for the proposed new use on citrus.
- Further, the company contends that, since there are already tolerances established for the use on citrus, the agency does not need to make a safety finding to support these new uses.

Benefits

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives.
- Use of aldicarb tends to produce higher yields.
- Based on the broad-spectrum nature of this carbamate, it is likely to control the Asian citrus psyllid; however, aldicarb's role in controlling citrus greening and whether it is more efficacious than the 13 alternatives (including the recent registration of sulfoxaflor on citrus) are unknown.

Ex. 5 Deliberative Process (DP)

EPA's Current Evaluation of the Requested Use on Citrus in Florida and Texas

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Confidential/Internal/Deliberative DRAFT

Aldicarb Proposed Use on Citrus Issue Paper
DRAFT January 14, 2020

Issue

AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. OPP met with the registrant to discuss the specific risk concerns with the proposed new uses for this active ingredient. Understanding the challenges, the registrant elected to make a submission on April 9, 2019. The PRIA due date for this action is July 15, 2020. Having completed review of the submission, Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Regulatory History

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity, and to protect ground water.
- Aldicarb products are currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. There are no registered residential uses of aldicarb.
- In 2010, Bayer (the registrant at that time) voluntarily agreed to cancel the domestic aldicarb uses on citrus (and potatoes), due to the findings by EPA that the registered uses posed an unacceptable dietary risk, especially to infants and young children. However, the existing tolerances for citrus have been maintained to allow for treated imports. Further, the registrant adopted risk mitigation measures for the remaining uses to protect groundwater resources.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.
    - The EPA risk assessment for the 2017 ID depicted risk estimates for dietary (food only) exposure below the level of concern, which included citrus exposure from imported commodities only.
    - Ex. 5 Deliberative Process (DP)

Current Submission

- To support the registration of aldicarb on citrus in Florida and Texas, AgLogic did not submit new data, but instead conducted their own dietary exposure and drinking water exposure assessments. The company asserts that these analyses demonstrate that there are no risks of concern for the proposed new use on citrus.
- Further, the company contends that, since there are already tolerances established for the use on citrus, the agency does not need to make a safety finding to support these new uses.

Ex. 5 Deliberative Process (DP)

Benefits

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives.
- Use of aldicarb tends to produce higher yields.
- Based on the broad-spectrum nature of this carbamate, it is likely to control the Asian citrus psyllid; however, aldicarb's role in controlling citrus greening and whether it is more efficacious than the 13 alternatives (including the recent registration of sulfoxaflor on citrus) are unknown.
- Additionally, the projected percent crop treatment (%CT) of the proposed use on orange and grapefruit in Texas and Florida is expected to result in at least the following % CT for the citrus commodities: oranges (65%), orange juice (85%), grapefruit (90%) and grapefruit juice (90%).

Ex. 5 Deliberative Process (DP)

EPA's Current Evaluation of the Requested Use on Citrus in Florida and Texas

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 1/13/2020 9:09:19 PM
To: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
CC: Rate, Debra [Rate.Debra@epa.gov]
Subject: FW: aldicarb.....
Attachments: Aldicarb Citrus New Use Summary Paper,m 1.13.20 dnr.docx

Fyi. . .

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Johnson, Marion
Sent: Monday, January 13, 2020 4:09 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Subject: FW: aldicarb.....

Debra,

Thanks for going through Mike's comments. I think we should go ahead and finalize what you've added. I put some of my thoughts into the comments section, so consider those and let me know what you think. As you will see, I

Ex. 5 Deliberative Process (DP)

Marion J.

Marion J. Johnson, Jr.
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(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Johnson, Marion
Sent: Monday, January 13, 2020 12:57 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: aldicarb.....

Ok. . . thanks! I'll take a look. I haven't had any time this morning to review Mike's comments, but hope to spend some time this afternoon to do so.

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
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(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, January 13, 2020 12:08 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: aldicarb.....

Hi Marion,

Attached are some thoughts on Mikes comments.

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Confidential/Internal/Deliberative DRAFT

Aldicarb Proposed Use on Citrus Issue Paper
DRAFT January 13, 2020

Issue

AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. OPP met with the registrant to discuss the specific risk concerns with the proposed new uses for this active ingredient. Understanding the challenges, the registrant elected to make a submission on April 9, 2019. The PRIA due date for this action is July 15, 2020. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Regulatory History

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- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
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    - The EPA risk assessment for the 2017 ID depicted risk estimates for dietary (food only) exposure below the level of concern, which included citrus exposure from imported commodities only.

Ex. 5 Deliberative Process (DP)

Current Submission

- To support the registration of aldicarb on citrus in Florida and Texas, AgLogic did not submit new data, but instead conducted their own dietary exposure and drinking water exposure assessments. The company asserts that these analyses demonstrate that there are no risks of concern for the proposed new use on citrus.
- Further, the company contends that, since there are already tolerances established for the use on citrus, the agency does not need to make a safety finding to support these new uses.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 1/13/2020 5:07:34 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: aldicarb.....
Attachments: Aldicarb Citrus New Use Summary Paper 1.13.20 dnr.docx

Hi Marion,

Attached are some thoughts on Mikes comments.

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Confidential/Internal/Deliberative DRAFT

Aldicarb Proposed Use on Citrus Issue Paper
DRAFT January 13, 2020

Issue
AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. OPP met with the registrant to discuss the specific risk concerns with the proposed new uses for this active ingredient. Understanding the challenges, the registrant elected to make a submission on April 9, 2019. The PRIA due date for this action is July 15, 2020. Having completed review of the submission, OPP has identified significant risks of concern that prevent moving forward with the requested new uses. OPP would like to alert the interested parties of our findings as soon as possible. There has been congressional interest on the progress and pending outcome of this application.

Regulatory History
- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity, and to protect ground water.
- Aldicarb products are currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. There are no registered residential uses of aldicarb.
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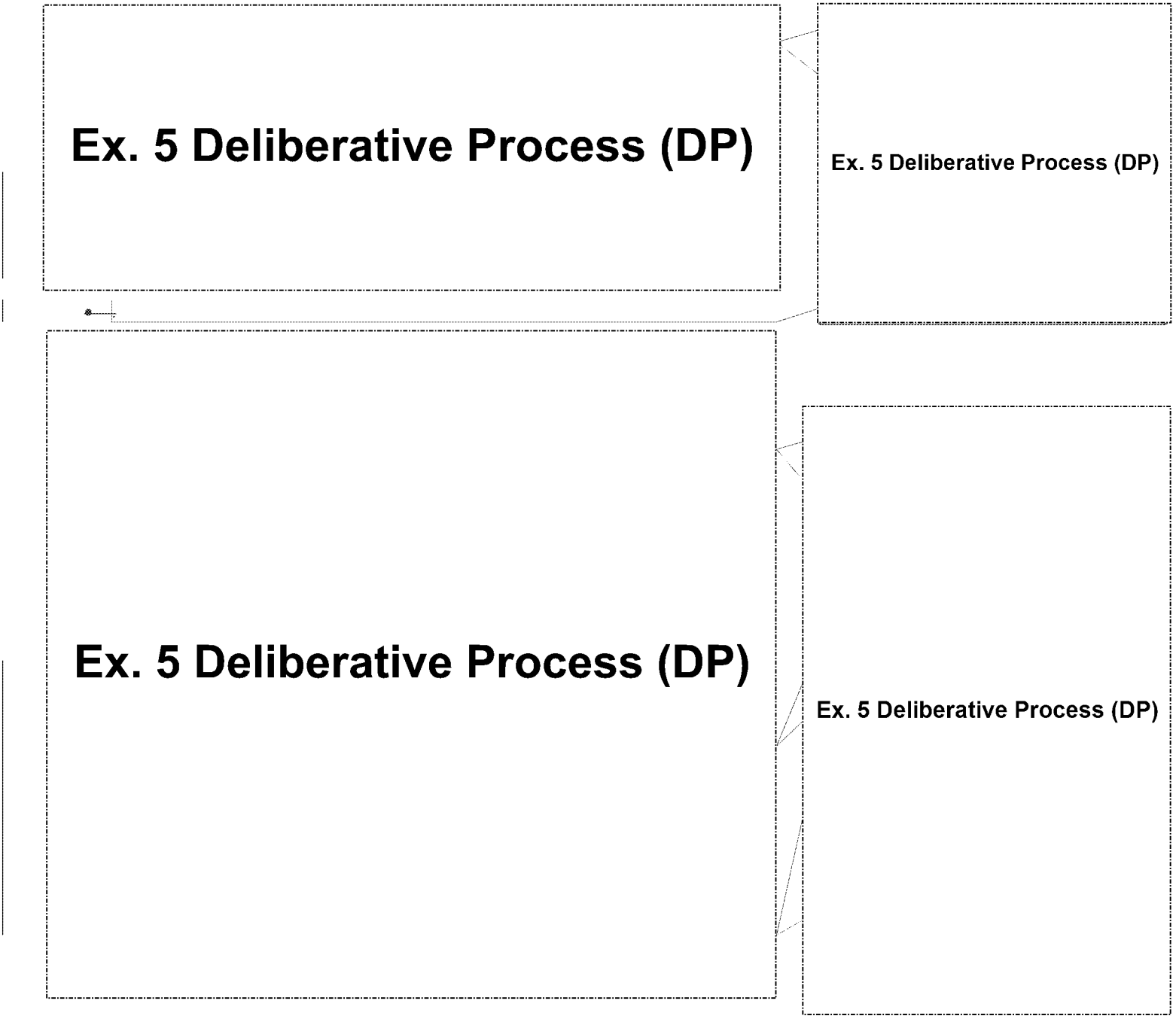
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.

Ex. 5 Deliberative Process (DP)

Current Submission
- To support the registration of aldicarb on citrus in Florida and Texas, AgLogic did not submit new data, but instead conducted their own dietary exposure and drinking water exposure assessments. The company asserts that these analyses demonstrate that there are no risks of concern for the proposed new use on citrus.
- Further, the company contends that, since there are already tolerances established for the use on citrus, the agency does not need to make a safety finding to support these new uses.

Ex. 5 Deliberative Process (DP)


Ex. 5 Deliberative Process (DP)
Ex. 5 Deliberative Process (DP)
Ex. 5 Deliberative Process (DP)
Ex. 5 Deliberative Process (DP)

registered.

Ex. 5 Deliberative Process (DP)

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 1/9/2020 10:16:23 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]
Subject: RE: Aldicarb Memo
Attachments: Aldicarb Citrus New Use_one pagermjjj12 30 19 (002).docx

Importance: High

Mike, et.al.:

Please disregard the first document below, as I failed to "delete all comments". I'm attaching the final edited document, as required. Many thanks!

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Johnson, Marion
Sent: Thursday, January 9, 2020 12:14 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Mike,

Attached is the most updated aldicarb "one pager" which incorporates responses to your questions/comments The second document contains your original comments and has been provided for comparison purposes only, as track changes were becoming too distracting. Thus, we think that we've addressed your thoughts, while still keeping the document tailored and structured to the AA's needs. However, let us know, if you have further questions.

Marion J.

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Chief, Invertebrate-Vertebrate Branch 2
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(703) 308-0029 (fax)
Johnson.marion@epa.gov

Visit: http://www/epa.gov/pesticides

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Monday, December 30, 2019 2:57 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Monday, December 23, 2019 11:45 AM
To: Davis, Donna <Davis.Donna@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Donna, et. al.:

Thanks for pulling this together. **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) Otherwise, I'm fine with this version but let me know if you have additional thoughts.

Best regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Davis, Donna <Davis.Donna@epa.gov>
Sent: Friday, December 20, 2019 10:41 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

I took a run at developing a document that I think is the right level of detail and tone for briefing the AA.

Mike/Dan,
Please advise if this is the right level of detail to brief up.

Marion/Debra,
If Mike/Dan concur this works, I suspect it needs a little more work and a few tweaks, but can you take the lead in finalizing?

Donna

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Thursday, December 19, 2019 1:27 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Davis, Donna <Davis.Donna@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: FW: Aldicarb Memo
Importance: High

Mike,

Ex. 5 Deliberative Process (DP)

Regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
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Visit: http://www/epa.gov/pesticides

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, December 19, 2019 12:51 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb memo - corrected

Marion,

I made the corrections to the memo that you dropped off and we discussed in this version.
Thanks,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Aldicarb Proposed Use on Citrus Issue Paper
DRAFT December 20, 2019

Issue

AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. Ex. 5 Deliberative Process (DP) specific challenges with the proposed new uses Ex. 5 Deliberative Process (DP) The PRIA due date for this action is July 15, 2020. Having completed review of the submission, Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) OPP would like to alert the interested parties of our findings as soon as possible. There has been congressional interest in this application.

Regulatory History

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity and to protect ground water.
- Aldicarb products are currently registered for use in agricultural areas on cotton, dry beans (CO, OR,WA, ID, MI), peanuts, soybeans (GA, NC, SC, VA), sugar beets (CA, CO, ID, MT, NE, OR, WA, WY), and sweet potatoes (LA, MS). There are no registered residential uses of aldicarb.
- The requested use on citrus was previously supported by Bayer prior to cancellation, but existing tolerances for citrus have been maintained to allow for treated imports. In 2010, Bayer voluntarily agreed to cancel the domestic aldicarb uses on citrus and potatoes due to the findings by EPA that the registered uses posed an unacceptable dietary risk, especially to infants and young children. Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) Further, the registrant adopted risk mitigation measures for the remaining uses to protect groundwater resources.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Current Submission

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Benefits

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives.
- Use of aldicarb tends to produce higher yields.
- Aldicarb will provide another tool in the toolbox for growers to control Asian citrus psyllid. Based on the broad-spectrum nature of this carbamate, it is likely to kill the psyllid; however, aldicarb's role in controlling citrus greening and whether it is more efficacious than the 13 alternatives listed below are unknown.

Alternatives

- Florida Citrus Production Guide ([HYPERLINK "http://www.crec.ifas.ufl.edu/resources/production-guide/"]) list the following 12 alternative insecticides as having good control for psyllid: beta-cyfluthrin, chlorpyrifos, cyantraniliprole, dimethoate, fenpropathrin, fenpyroximate, phosmet, spinetoram, spirotetramat, thiamethoxam, tolfenpyrad, zeta-cypermethrin. In addition, EPA recently approved sulfoxaflor for use on citrus.

EPA's Current Evaluation of the Requested Use on Citrus in Florida and Texas

- OPP technical experts reviewed the white papers and analyses submitted by the registrant. The white papers suggested Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

- Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

-

Ex. 5 Deliberative Process (DP)

- Ex. 5 Deliberative Process (DP)

Proposed Next Steps

Ex. 5 Deliberative Process (DP)

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 1/9/2020 5:14:16 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]
Subject: RE: Aldicarb Memo
Attachments: Aldicarb Citrus New Use_one pagermjj12 30 19 (002).docx; Aldicarb Citrus New Use_one pager 12 30 19.docx

Mike,

Attached is the most updated aldicarb "one pager" which incorporates responses to your questions/comments The second document contains your original comments and has been provided for comparison purposes only, as track changes were becoming too distracting. Thus, we think that we've addressed your thoughts, while still keeping the document tailored and structured to the AA's needs. However, let us know, if you have further questions.

Marion J.

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Subject: RE: Aldicarb Memo

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.
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Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

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<Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Donna, et. al.:

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Ex. 5 Deliberative Process (DP)

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Subject: FW: Aldicarb Memo
Importance: High

Mike,

Ex. 5 Deliberative Process (DP)

Regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, December 19, 2019 12:51 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb memo - corrected

Marion,

I made the corrections to the memo that you dropped off and we discussed in this version.
Thanks,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Confidential/Internal/Deliberative DRAFT

Aldicarb Proposed Use on Citrus Issue Paper
DRAFT December 20, 2019

Issue

AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. OPP met with the registrant to discuss the specific challenges with the proposed new uses for this active ingredient. Understanding the challenges, the registrant elected to make a submission on April 9, 2019. The PRIA due date for this action is July 15, 2020. Having completed review of the submission, Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) OPP would like to alert the interested parties of our findings as soon as possible. There has been congressional interest in this application.

Regulatory History

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity and to protect ground water.
- Aldicarb products are currently registered for use in agricultural areas on cotton, dry beans (CO, OR,WA, ID, MI), peanuts, soybeans (GA, NC, SC, VA), sugar beets (CA, CO, ID, MT, NE, OR, WA, WY), and sweet potatoes (LA, MS). There are no registered residential uses of aldicarb.
- The requested use on citrus was previously supported by Bayer prior to cancellation, but existing tolerances for citrus have been maintained to allow for treated imports. In 2010, Bayer voluntarily agreed to cancel the domestic aldicarb uses on citrus and potatoes due to the findings by EPA that the registered uses posed an unacceptable dietary risk, especially to infants and young children. Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) Further, the registrant adopted risk mitigation measures for the remaining uses to protect groundwater resources.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Current Submission

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Benefits

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives.
- Use of aldicarb tends to produce higher yields.
- Aldicarb will provide another tool in the toolbox for growers to control Asian citrus psyllid. Based on the broad-spectrum nature of this carbamate, it is likely to kill the psyllid; however, aldicarb's role in controlling citrus greening and whether it is more efficacious than the 13 alternatives listed below are unknown.

Alternatives

- Florida Citrus Production Guide ([HYPERLINK "http://www.crec.ifas.ufl.edu/resources/production-guide/"]) list the following 12 alternative insecticides as having good control for psyllid: beta-cyfluthrin, chlorpyrifos, cyantraniliprole, dimethoate, fenpropathrin, fenpyroximate, phosmet, spinetoram, spirotetramat, thiamethoxam, tolfenpyrad, zeta-cypermethrin. In addition, EPA recently approved sulfoxaflor for use on citrus.

EPA's Current Evaluation of the Requested Use on Citrus in Florida and Texas

- Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

- Ex. 5 Deliberative Process (DP)
- Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

- Ex. 5 Deliberative Process (DP)

Proposed Next Steps

Ex. 5 Deliberative Process (DP)

Confidential/Internal/Deliberative DRAFT

Aldicarb Proposed Use on Citrus Issue Paper
DRAFT December 20, 2019

Issue

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- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity and to protect ground water.
- Aldicarb products are currently registered for use in agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. There are no registered residential uses of aldicarb.
- The requested use on citrus were previously supported by Bayer, and there are existing tolerances for use on citrus which have not been revoked. In 2010, Bayer voluntarily agreed to cancellation for aldicarb due to the findings by EPA that the registered uses posed an unacceptable dietary risk, especially to infants and young children. To address the most significant risks, Bayer agree to immediately end use on citrus and potatoes. Further, the registrant adopted risk mitigation measures for the remaining uses to protect groundwater resources.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Current Submission

Ex. 5 Deliberative Process (DP)

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- Ex. 5 Deliberative Process (DP)
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Ex. 5 Deliberative Process (DP)

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EPA's Evaluation of the Requested Use

- OPP technical experts reviewed the white papers and analyses submitted by the registrant. The white papers suggested Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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-
-

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Proposed Next Steps

Ex. 5 Deliberative Process (DP)

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 1/8/2020 1:12:25 PM
To: Rate, Debra [Rate.Debra@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: aldicarb memo

Thanks, Debra! I didn't work on this yesterday after leaving the office, but I'll look at it thoroughly this morning. Since Mike is out, I'm hoping I'll have a glut of time this morning if the staff meeting is cancelled.

MJJ

Marion J. Johnson, Jr.
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Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, January 7, 2020 3:51 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: aldicarb memo

Hi,

I've been trying to read and capture answers for Mike's comments in the aldicarb memo. I made a couple of tweaks to the memo, but concentrated mostly on replies to the comments. There is one comment highlighted in yellow, where I did not quite know where Mike was heading or wanting for the memo?

Thanks.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 1/7/2020 8:51:16 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: aldicarb memo
Attachments: Aldicarb Citrus New Use_one pager 12 30 19 dnr.docx

Hi,

I've been trying to read and capture answers for Mike's comments in the aldicarb memo. I made a couple of tweaks to the memo, but concentrated mostly on replies to the comments. There is one comment highlighted in yellow, where I did not quite know where Mike was heading or wanting for the memo?

Thanks.
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U.S. Environmental Protection Agency

Phone: 703-306-0309

Confidential/Internal/Deliberative DRAFT

Aldicarb Proposed Use on Citrus Issue Paper
DRAFT December 20, 2019

Issue

AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. OPP met with the registrant to discuss the specific challenges with the proposed new uses for this active ingredient. Understanding the challenges, the registrant elected to make a submission on April 9, 2019. The PRIA due date for this action is July 15, 2020. Having completed review of the submission, Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) OPP would like to alert the interested parties of our findings as soon as possible. There has been congressional interest in this application.

Regulatory History

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity and to protect ground water.
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- Ex. 5 Deliberative Process (DP) the most significant risks, Bayer agree to immediately end use on citrus and potatoes. Further, the registrant adopted risk mitigation measures for the remaining uses to protect groundwater resources.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.

Current Submission

Ex. 5 Deliberative Process (DP)

Benefits

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Alternatives

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EPA's Evaluation of the Requested Use

- OPP technical experts reviewed the white papers and analyses submitted by the registrant. The white papers suggested

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

- Ex. 5 Deliberative Process (DP)
- Ex. 5 Deliberative Process (DP)
- Ex. 5 Deliberative Process (DP)

Proposed Next Steps

Ex. 5 Deliberative Process (DP)

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 12/20/2019 6:48:35 PM
To: Davis, Donna [Davis.Donna@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]
Subject: RE: Aldicarb Memo

Thanks, Donna! I'm reviewing it now. . .

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
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(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Davis, Donna <Davis.Donna@epa.gov>
Sent: Friday, December 20, 2019 10:41 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

I took a run at developing a document that I think is the right level of detail and tone for briefing the AA.

Mike/Dan,
Please advise if this is the right level of detail to brief up.

Marion/Debra,
If Mike/Dan concur this works, I suspect it needs a little more work and a few tweaks, but can you take the lead in finalizing?

Donna

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Thursday, December 19, 2019 1:27 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Davis, Donna <Davis.Donna@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: FW: Aldicarb Memo
Importance: High

Mike,

Ex. 5 Deliberative Process (DP)

Regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
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Visit: http://www/epa.gov/pesticides

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, December 19, 2019 12:51 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb memo - corrected

Marion,

I made the corrections to the memo that you dropped off and we discussed in this version.
Thanks,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Davis, Donna [Davis.Donna@epa.gov]
Sent: 12/20/2019 3:41:28 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]
Subject: RE: Aldicarb Memo
Attachments: Aldicarb Citrus New Use_one pager 12 20 19.docx

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Subject: FW: Aldicarb Memo
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Mike,

Ex. 5 Deliberative Process (DP)

Regards,

Marion J.

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U.S. Environmental Protection Agency

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Aldicarb Proposed Use on Citrus Issue Paper
DRAFT December 20, 2019

Issue

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Regulatory History

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Current Submission

Ex. 5 Deliberative Process (DP)

Benefits

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- Use of aldicarb tends to produce higher yields.
- Ex. 5 Deliberative Process (DP)
- Aldicarb will provide another tool in the toolbox for growers to control Asian citrus psyllid. Based on the broad-spectrum nature of this carbamate, it is likely to kill the psyllid; however, aldicarb's role in controlling citrus greening and whether it is more efficacious than the 13 alternatives listed below are unknown.

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EPA's Evaluation of the Requested Use

- Ex. 5 Deliberative Process (DP)
- Ex. 5 Deliberative Process (DP)
- Ex. 5 Deliberative Process (DP)
- Ex. 5 Deliberative Process (DP)
- Ex. 5 Deliberative Process (DP)

Proposed Next Steps

Ex. 5 Deliberative Process (DP)

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 12/19/2019 5:51:28 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Aldicarb memo - corrected
Attachments: One pager Aldicarb 12.18.19 ver4.docx

Marion,

I made the corrections to the memo that you dropped off and we discussed in this version.
Thanks,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 12/19/2019 1:54:26 PM
To: Rate, Debra [Rate.Debra@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Next version - Aldicarb memo

Okay. . . thank you! I have a meeting with Donna and Betty at 9:00 a.m.; so, I'll take a look immediately after that.

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
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Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
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Visit: http://www/epa.gov/pesticides

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, December 19, 2019 8:50 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Next version - Aldicarb memo

Hi Marion,

Here is the next version of the aldicarb briefing paper based on our conversion yesterday.

Thanks.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 12/19/2019 1:49:38 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Next version - Aldicarb memo
Attachments: One pager Aldicarb 12.18.19 ver3.docx

Hi Marion,

Here is the next version of the aldicarb briefing paper based on our conversion yesterday.

Thanks.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Purpose:

Provide OCSPP/OPP management with synopsis of pending aldicarb submission, Agency response and recommended path forward.

Background on Submission:

- AgLogic Chemical LLC (AgLogic) has submitted an application for registration of new uses of oranges and grapefruit in Florida and Texas (PRIA due date July 15, 2020).
  - Uses previously supported by Bayer prior to its decision to voluntarily cancel these and other uses in 2010.
- AgLogic contends that Ex. 5 Deliberative Process (DP)
  - Ex. 5 Deliberative Process (DP)
- AgLogic likely to argue Ex. 5 Deliberative Process (DP)
  - Ex. 5 Deliberative Process (DP)
  - Ex. 5 Deliberative Process (DP)
  - Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Conclusions:

-
- Ex. 5 Deliberative Process (DP)
-

Next Steps:

- Communication with the company will be initiated.
- Ex. 5 Deliberative Process (DP)
-

Supplemental Background Information

Background:

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity and to protect ground water.
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- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.

Current Action:

- AgLogic Chemical LLC submitted an application on April 9, 2019 for registration of new uses of citrus (grapefruit and oranges) in Florida and Texas. The PRIA due date for this submission is July 15, 2020.
- There is no tolerance petition associated with the action as tolerances are established for grapefruit and orange, sweet, a use supported by Bayer prior to its decision to voluntarily cancel these and other uses in 2010.
- AgLogic Chemical LLC provided four (4) studies with the current action. They include the following:
    - White paper arguing the correct lateral flow velocity to use in assessment for drinking water.
    - White paper: Updated dietary (food + water) assessment (20 pages)
    - White paper: Updated dietary (food + water) assessment (272 pages – company's updated version)
    - White paper: Drinking water exposure assessment
- Citrus pests listed on the proposed label include Asian citrus psyllid (responsible for transmission of citrus greening); mites; aphids; whiteflies; and nematodes.

Benefits:

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives.
- Use of aldicarb tends to produce higher yields.
- **Ex. 5 Deliberative Process (DP)**
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- phosmet, spinetoram, spirotetramat, thiamethoxam, tolfenpyrad, zeta-cypermethrin. In addition, EPA recently approved sulfoxaflor for use on citrus.

Risks of Concern:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Initial Conclusions:

Ex. 5 Deliberative Process (DP)

Additional Evaluation Areas:

Ex. 5 Deliberative Process (DP)

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 12/17/2019 2:40:58 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb one-pager
Attachments: One pager Aldicarb 12.16.19.docx

I'm working on it. I have attached the beginnings of the new version. I'm struggling with the addition of the new page to the rest of the "background".

Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Monday, December 16, 2019 3:05 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Aldicarb one-pager
Importance: High

Debra:

When you get a chance, let's discuss where we are in response to Donna's latest questions on the aldicarb white paper. Mike asked me about the status during a meeting with him yesterday. Many thanks!

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, December 5, 2019 12:28 PM
To: Davis, Donna <Davis.Donna@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb one-pager

Hi Mike,

As I mentioned to you, earlier, we will be working to revise the one-pager and gathering the answers to the questions Donna raised and other questions we think may be raised by the registrant and growers.

Thanks.
Debra

From: Davis, Donna <Davis.Donna@epa.gov>
Sent: Tuesday, December 03, 2019 1:42 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb one-pager

Ex. 5 Deliberative Process (DP)

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Tuesday, December 3, 2019 10:46 AM
To: Davis, Donna <Davis.Donna@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb one-pager
Importance: High

Ex. 5 Deliberative Process (DP)

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Office of Pesticide Programs
Registration Division
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(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Davis, Donna <Davis.Donna@epa.gov>
Sent: Monday, December 2, 2019 10:03 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>

Cc: Goodis, Michael <Goodis.Michael@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: Aldicarb one-pager

Debra,
Can you do an updated one-pager with the information you provided? We will need to get that to Rick to see if more is needed. Is that something you all can do today?
Donna

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 12/3/2019 7:41:08 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb one-pager

Ex. 5 Deliberative Process (DP)

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Tuesday, December 03, 2019 2:20 PM
To: Davis, Donna <Davis.Donna@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb one-pager

Ex. 5 Deliberative Process (DP)

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From: Davis, Donna <Davis.Donna@epa.gov>
Sent: Tuesday, December 3, 2019 1:42 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb one-pager

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Sent: Tuesday, December 3, 2019 10:46 AM
To: Davis, Donna <Davis.Donna@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb one-pager
Importance: High

Donna, Mike:

Debra provided me with the final aldicarb one-pager this morning, as a result of our discussions late yesterday. EFED has weighed in our remaining questions, and we've included those responses within the document. Please let us know, if either of you have any remaining questions, and if you'd like for us to walk you through the contents of the one-pager. Many thanks!

Regards,

Marion

J.

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(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

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Sent: Monday, December 2, 2019 10:03 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>

Cc: Goodis, Michael <Goodis.Michael@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: Aldicarb one-pager

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Donna

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 12/3/2019 3:46:18 PM
To: Davis, Donna [Davis.Donna@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb one-pager
Attachments: One pager Aldicarb 12.2.19.docx

Importance: High

Donna, Mike:

Debra provided me with the final aldicarb one-pager this morning, as a result of our discussions late yesterday. EFED has weighed in our remaining questions, and we've included those responses within the document. Please let us know, if either of you have any remaining questions, and if you'd like for us to walk you through the contents of the one-pager. Many thanks!

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Marion

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Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Davis, Donna <Davis.Donna@epa.gov>
Sent: Monday, December 2, 2019 10:03 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Goodis, Michael <Goodis.Michael@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: Aldicarb one-pager

Debra,
Can you do an updated one-pager with the information you provided? We will need to get that to Rick to see if more is needed. Is that something you all can do today?
Donna

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 12/2/2019 10:07:26 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb - Updating one pager
Attachments: One pager Aldicarb 12.2.19.docx

Hi,

I think I have properly incorporated Amy's (EFED) comments. I left a couple of her questions in the memo as a reminder to make sure that they were addressed.
Please have a look and see if you think I missed anything.
Thanks.
Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Monday, December 02, 2019 12:30 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Updating one pager
Importance: High

Debra,

I've added some comments for consideration, but they're not absolute; so, let me know your thoughts. Also, just ensure that the fonts are all the same as I believe I detected some disparate fonts, probably due to cutting and pasting. Many thanks!

Marion J.

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(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Johnson, Marion
Sent: Monday, December 2, 2019 10:42 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Updating one pager

I'm looking at it now.

MJJ

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(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, December 2, 2019 10:34 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Aldicarb - Updating one pager

Donna asked for this by today. See what you think of the updated one-pager.

I will ask Amy if there is any chance EFED can look at this today.

Debra

From: Rate, Debra
Sent: Tuesday, November 26, 2019 1:42 PM
To: Blankinship, Amy <Blankinship.Amy@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb - Updating one pager

Hi Amy,

Ex. 5 Deliberative Process (DP)

Thank you!
Debra

From: Blankinship, Amy <Blankinship.Amy@epa.gov>
Sent: Wednesday, November 20, 2019 9:59 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: aldicarb meeting

Internal deliberative, do not cite

Attached is the latest EFED EDWCs for the new use that might be helpful for the conversation/meeting.

Amy

From: Blankinship, Amy
Sent: Wednesday, November 20, 2019 9:54 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Subject: aldicarb meeting

When is the aldicarb meeting? Today or tomorrow at 2 pm? I don't see the calendar invite.

Thanks,
Amy

Amy Blankinship
Branch Chief, ERB2
USEPA – OCSPP/OPP/EFED
703-347-8062

Message

From: Blankinship, Amy [Blankinship.Amy@epa.gov]
Sent: 12/2/2019 8:52:06 PM
To: Rate, Debra [Rate.Debra@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Lin, James [lin.james@epa.gov]; Wente, Stephen [Wente.Stephen@epa.gov]; Arnold, Elyssa [Arnold.Elyssa@epa.gov]
Subject: RE: Aldicarb - Updating one pager
Attachments: One pager Aldicarb 11.26.19 (SPW Edits)_ab.docx

Hi Debra,

Attached are EFED's comments. Let us know if you have any questions.

Amy

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, December 02, 2019 2:30 PM
To: Blankinship, Amy <Blankinship.Amy@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Lin, James <lin.james@epa.gov>; Wente, Stephen <Wente.Stephen@epa.gov>; Arnold, Elyssa <Arnold.Elyssa@epa.gov>
Subject: RE: Aldicarb - Updating one pager

Thank you!

From: Blankinship, Amy <Blankinship.Amy@epa.gov>
Sent: Monday, December 02, 2019 2:21 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Lin, James <lin.james@epa.gov>; Wente, Stephen <Wente.Stephen@epa.gov>; Arnold, Elyssa <Arnold.Elyssa@epa.gov>
Subject: RE: Aldicarb - Updating one pager

We are working on it now.

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, December 02, 2019 2:06 PM
To: Blankinship, Amy <Blankinship.Amy@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Lin, James <lin.james@epa.gov>; Wente, Stephen <Wente.Stephen@epa.gov>; Arnold, Elyssa <Arnold.Elyssa@epa.gov>
Subject: RE: Aldicarb - Updating one pager

Hi Amy,

Sorry to have to ask….but my IO asked if there would be any way for your group to comment on the one-pager by COB today?

Please let me know.
Thanks.
Debra

From: Blankinship, Amy <Blankinship.Amy@epa.gov>
Sent: Wednesday, November 27, 2019 11:56 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Lin, James <lin.james@epa.gov>; Wente, Stephen <Wente.Stephen@epa.gov>; Arnold, Elyssa <Arnold.Elyssa@epa.gov>
Subject: RE: Aldicarb - Updating one pager

That will work. Thanks for getting back to me.

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Wednesday, November 27, 2019 10:43 AM
To: Blankinship, Amy <Blankinship.Amy@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Updating one pager

I know this is a big ask with all of the holidays, but would you be able to provide comments next week? (Maybe Wednesday?)

Thanks!
Debra

From: Blankinship, Amy <Blankinship.Amy@epa.gov>
Sent: Wednesday, November 27, 2019 9:30 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Updating one pager

Thanks Debra. We'll take a look at this. When do you need comments back by?

Amy

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, November 26, 2019 1:42 PM
To: Blankinship, Amy <Blankinship.Amy@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb - Updating one pager

Hi Amy,

Ex. 5 Deliberative Process (DP)

Thank you!
Debra

From: Blankinship, Amy <Blankinship.Amy@epa.gov>
Sent: Wednesday, November 20, 2019 9:59 AM

To: Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: aldicarb meeting

Internal deliberative, do not cite

Attached is the latest EFED EDWCs for the new use that might be helpful for the conversation/meeting.

Amy

From: Blankinship, Amy
Sent: Wednesday, November 20, 2019 9:54 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Subject: aldicarb meeting

When is the aldicarb meeting? Today or tomorrow at 2 pm? I don't see the calendar invite.

Thanks,
Amy

Amy Blankinship
Branch Chief, ERB2
USEPA – OCSPP/OPP/EFED
703-347-8062

Internal/Confidential/Deliberative

Aldicarb – Proposed Use on Citrus (Grapefruit and Oranges)
November 26, 2019

Background:

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity and to protect ground water.
- Aldicarb products are currently registered for use in agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. There are no registered residential uses of aldicarb.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.

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Current Action:

- AgLogic Chemical LLC submitted an application on April 9, 2019 for registration of new uses of citrus (grapefruit and oranges) in Florida and Texas. -The PRIA due date for this submission is July 15, 2020.
- There is no tolerance petition associated with the action as tolerances are established for grapefruit and orange, sweet, a use supported by Bayer prior to its decision to voluntarily cancel these and other uses in 2010.
- AgLogic Chemical LLC provided four (4) studies with the current action. They include the following:
  - White paper arguing the correct lateral flow velocity to use in assessment for drinking water.
  - White paper: Updated dietary (food + water) assessment (20 pages)
  - White paper: Updated dietary (food + water) assessment (272 pages – company's updated version)
  - White paper: Drinking water exposure assessment
- Citrus pests listed on the proposed label include Asian citrus psyllid (responsible for transmission of citrus greening); mites; aphids; whiteflies; and nematodes.

Benefits:

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives.
- Use of aldicarb tends to produce higher yields.
- Aldicarb is one of only four currently registered, non-fumigant nematicides.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Alternatives:

- Florida Citrus Production Guide ([HYPERLINK "http://www.crec.ifas.ufl.edu/resources/production-guide/"]) list the following 12

alternative insecticides as having good control for psyllid: beta-cyfluthrin, chlorpyrifos, cyantraniliprole, dimethoate, fenpropathrin, fenpyroximate,

- phosmet, spinetoram, spirotetramat, thiamethoxam, tolfenpyrad, zeta-cypermethrin. In addition, EPA recently approved sulfoxaflor for use on citrus.

Ex. 5 Deliberative Process (DP)

Drinking Water (Previous Uses):

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

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Initial Conclusions:

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Additional Evaluation Areas:

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Next Steps:

Ex. 5 Deliberative Process (DP)

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Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 12/2/2019 5:30:17 PM
To: Rate, Debra [Rate.Debra@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb - Updating one pager
Attachments: One pager Aldicarb 11.26.19.docx

Importance: High

Debra,

I've added some comments for consideration, but they're not absolute; so, let me know your thoughts. Also, just ensure that the fonts are all the same as I believe I detected some disparate fonts, probably due to cutting and pasting. Many thanks!

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Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Johnson, Marion
Sent: Monday, December 2, 2019 10:42 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Updating one pager

I'm looking at it now.

MJJ

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To: Johnson, Marion <Johnson.Marion@epa.gov>

Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Aldicarb - Updating one pager

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Sent: Tuesday, November 26, 2019 1:42 PM
To: Blankinship, Amy <Blankinship.Amy@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb - Updating one pager

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Ex. 5 Deliberative Process (DP)

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Subject: RE: aldicarb meeting

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Branch Chief, ERB2
USEPA – OCSPP/OPP/EFED

703-347-8062

Internal/Confidential/Deliberative

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November 26, 2019

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    - White paper: Updated dietary (food + water) assessment (20 pages)
    - White paper: Updated dietary (food + water) assessment (272 pages – company's updated version)
    - White paper: Drinking water exposure assessment
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Ex. 5 Deliberative Process (DP)

alternative insecticides as having good control for psyllid: beta-cyfluthrin, chlorpyrifos, cyantraniliprole, dimethoate, fenpropathrin, fenpyroximate,

- phosmet, spinetoram, spirotetramat, thiamethoxam, tolfenpyrad, zeta-cypermethrin. In addition, EPA recently approved sulfoxaflor for use on citrus.

Risks of Concern:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Initial Conclusions:

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Additional Evaluation Areas:

Ex. 5 Deliberative Process (DP)

Next Steps:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Message

From: Davis, Donna [Davis.Donna@epa.gov]
Sent: 11/27/2019 3:53:46 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Walsh, Michael [Walsh.Michael@epa.gov]
Subject: RE: Aldicarb

That's very helpful! Thanks very much Debra.

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Wednesday, November 27, 2019 10:39 AM
To: Davis, Donna <Davis.Donna@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Walsh, Michael <Walsh.Michael@epa.gov>
Subject: RE: Aldicarb

Hi Donna,

From: Davis, Donna <Davis.Donna@epa.gov>
Sent: Wednesday, November 27, 2019 6:31 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rosenblatt, Daniel

<Rosenblatt.Dan@epa.gov>
Subject: RE: Aldicarb

Ex. 5 Deliberative Process (DP)

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, November 26, 2019 4:58 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: RE: Aldicarb

Sorry I missed Donna and Dan on the update.

From: Rate, Debra
Sent: Tuesday, November 26, 2019 4:57 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Aldicarb
Importance: High

Hi Mike,

Ex. 5 Deliberative Process (DP)

Thanks,
Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Tuesday, November 26, 2019 8:46 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb
Importance: High

Mike-

Ex. 5 Deliberative Process (DP)

Regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Tuesday, November 26, 2019 7:23 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Subject: RE: Aldicarb

Marion

We have a general with Rick tomorrow. Any update on this action?

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Wednesday, November 20, 2019 1:59 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Subject: RE: Aldicarb

Mike,

We're meeting on aldicarb today, and I will bring these concerns up for group discussion and consideration.

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Friday, November 15, 2019 9:25 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Subject: Aldicarb

Marion

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Wednesday, November 13, 2019 11:37 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Subject: RE: Mike - I asked Anita this morning if we could reschedule my general some time later due to the crunch of meetings today (eom)

Ex. 5 Deliberative Process (DP)

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Wednesday, November 13, 2019 11:34 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Subject: RE: Mike - I asked Anita this morning if we could reschedule my general some time later due to the crunch of meetings today (eom)

OK

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Wednesday, November 13, 2019 11:34 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Subject: Mike - I asked Anita this morning if we could reschedule my general some time later due to the crunch of meetings today (eom)
Importance: High

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency

Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

Message

From: Waterworth, Rebeccah [Waterworth.Rebeccah@epa.gov]
Sent: 11/20/2019 4:14:29 PM
To: Metzger, Michael [Metzger.Michael@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Donovan, William [donovan.william@epa.gov]; Blankinship, Amy [Blankinship.Amy@epa.gov]; Arnold, Elyssa [Arnold.Elyssa@epa.gov]; Federoff, Nicholas [Federoff.Nicholas@epa.gov]; Koch, Erin [Koch.Erin@epa.gov]
Subject: Waterworth, Rebeccah shared "PCTn for Aldicarb (098301) in FL_TX citrus_20191108.esk" with you.

Waterworth, Rebeccah shared "PCTn for Aldicarb (098301) in FL_TX citrus_20191108.esk" with you.

This link only works for the direct recipients of this message.

PCTn for Aldicarb (098301) in FL_TX citrus_20191108.esk

Open

Microsoft respects your privacy. To learn more, please read our Privacy Statement.
Microsoft Corporation, One Microsoft Way, Redmond, WA 98052

Message

From: Rate, Debra [rate.debra@epa.gov]
Sent: 6/15/2020 1:28:05 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Conversation with Rate, Debra

Rate, Debra 6:59 AM:

Hi Shanta, I wanted to check in with you and Marion to see if you are OK with moving forward with the meeting this morning for aldicarb with the proposed agenda I sent out to you and Marion. It seemed to be the only 30 min slot available to all but one person in BEAD that I added.

Adeeb, Shanta 6:59 AM:
Hi Debr,

Adeeb, Shanta 7:00 AM:
I accepted the calendar invite this morning.

Adeeb, Shanta 7:00 AM:
I didn't see an agenda attached but I will search my emails for it.

Rate, Debra 7:01 AM:
I sent it out to you and Marion at about 8-9 pm last night.

Adeeb, Shanta 7:02 AM:
Ok.

Adeeb, Shanta 7:08 AM:
I just went through it. I have no objections to your agenda

Rate, Debra 7:10 AM:
OK. Thanks.

Adeeb, Shanta 9:02 AM:
Hi Debra,

9:03 AM This message wasn't sent to Rate, Debra.
Hi Debra,

Adeeb, Shanta 9:03 AM:
I asked the PMs if anyone had an example of a denial letter and no one. I wonder if Erin in OGC might have one since none of the PMs do

Adeeb, Shanta 9:04 AM:
Sorry for the delay in getting you this info

9:04 AM This message wasn't sent to Rate, Debra.
I asked the PMs if anyone had an example of a denial letter and no one. I wonder if Erin in OGC might have one since none of the PMs do

9:04 AM This message wasn't sent to Rate, Debra.
Sorry for the delay in getting you this info

Adeeb, Shanta 9:23 AM:
I asked the PMs if anyone had an example of a denial letter and no one. I wonder if Erin in OGC might have one since none of the PMs do

Adeeb, Shanta 9:23 AM:

Sorry for the delay in getting you this info

Rate, Debra 9:25 AM:

No worries.

Message

From: Rate, Debra [rate.debra@epa.gov]
Sent: 6/3/2020 7:14:27 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Conversation with Rate, Debra

Rate, Debra 2:58 PM:

Hello.

Adeeb, Shanta 2:59 PM:

hi

Rate, Debra 3:00 PM:

Ex. 5 Deliberative Process (DP)

Rate, Debra 3:11 PM:
Thanks!

Message

From: Rate, Debra [rate.debra@epa.gov]
Sent: 6/3/2020 7:08:39 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Conversation with Rate, Debra

Rate, Debra 2:58 PM:

Hello.

Adeeb, Shanta 2:59 PM:

hi

Ex. 5 Deliberative Process (DP)

Message

From: Adeeb, Shanta [adeeb.shanta@epa.gov]
Sent: 7/6/2020 3:49:56 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Quick Check-in: Aldicarb Remaining Strategy

Quick Check-in: Aldicarb Remaining Strategy

Rate, Debra
BIOLOGIST , OCSPP
Work: 703-306-0309
Email: rate.debra@epa.gov
IM: rate.debra@epa.gov

Johnson, Marion
SUPERVISORY BIOLOGIST , OCSPP
Work: 703-305-6788
Ex. 6 Personal Privacy (PP)
Email: johnson.marion@epa.gov
IM: johnson.marion@epa.gov

Skype for Business

Message

From: Rate, Debra [rate.debra@epa.gov]
Sent: 6/15/2020 1:05:49 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Conversation with Rate, Debra

Rate, Debra 6:59 AM:

Hi Shanta, I wanted to check in with you and Marion to see if you are OK with moving forward with the meeting this morning for aldicarb with the proposed agenda I sent out to you and Marion. It seemed to be the only 30 min slot available to all but one person in BEAD that I added.

Adeeb, Shanta 6:59 AM:
Hi Debr,

Adeeb, Shanta 7:00 AM:
I accepted the calendar invite this morning.

Adeeb, Shanta 7:00 AM:
I didn't see an agenda attached but I will search my emails for it.

Rate, Debra 7:01 AM:
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Ok.

Adeeb, Shanta 7:08 AM:
I just went through it. I have no objections to your agenda

Rate, Debra 7:10 AM:
OK. Thanks.

Adeeb, Shanta 9:02 AM:
Hi Debra,

9:03 AM This message wasn't sent to Rate, Debra.
Hi Debra,

Ex. 5 Deliberative Process (DP)

9:04 AM This message wasn't sent to Rate, Debra.
Sorry for the delay in getting you this info

Message

From: Rate, Debra [rate.debra@epa.gov]
Sent: 6/15/2020 11:22:08 AM
To: Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Conversation with Rate, Debra

Rate, Debra 6:59 AM:

Hi Shanta, I wanted to check in with you and Marion to see if you are OK with moving forward with the meeting this morning for aldicarb with the proposed agenda I sent out to you and Marion. It seemed to be the only 30 min slot available to all but one person in BEAD that I added.

Adeeb, Shanta 6:59 AM:
Hi Debr,

Adeeb, Shanta 7:00 AM:
I accepted the calendar invite this morning.

Adeeb, Shanta 7:00 AM:
I didn't see an agenda attached but I will search my emails for it.

Rate, Debra 7:01 AM:
I sent it out to you and Marion at about 8-9 pm last night.

Adeeb, Shanta 7:02 AM:
Ok.

Adeeb, Shanta 7:08 AM:
I just went through it. I have no objections to your agenda

Rate, Debra 7:10 AM:
OK. Thanks.

Message

From: Rate, Debra [rate.debra@epa.gov]
Sent: 6/11/2020 7:43:41 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Conversation with Johnson, Marion, Rate, Debra

Rate, Debra 3:17 PM:

Hi Marion, Shanta, [Ex. 5 Deliberative Process (DP)

A

R

J

Ex. 5 Deliberative Process (DP)

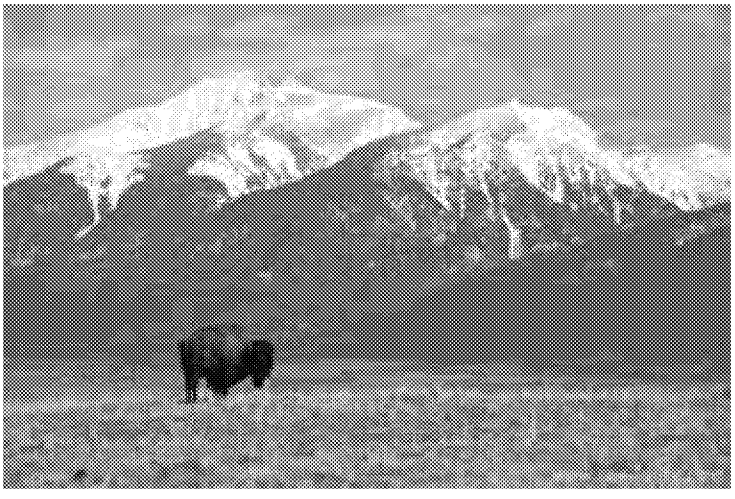
Adeeb, Shanta 3:19 PM:
Awesome

Adeeb, Shanta 3:20 PM:
I am going to be on the TcVP call this afternoon

Rate, Debra 3:21 PM:
I'd like to hear the TCVP discussion as well.

Adeeb, Shanta 3:30 PM:
Perfect

2018 CSKT
ANNUAL PESTICIDES SUMMARY REPORT



July 8, 2018 | Prepared for US EPA, Montana Office

Prepared by: Confederated Salish and Kootenai Tribes

Natural Resources Department

Division of Environmental Protection: Pesticides Program

With support from the US EPA Region 8 Analytical Lab

TABLE OF CONTENTS

Abbreviations and Acronyms

AWC	Anthropogenic organic waste compounds	RPD	Relative percent difference
CEC	Contaminant of Emerging Concern	TIC	Tentatively identified compound
CSKT	Confederated Salish and Kootenai Tribes	RL	Reporting level
HBSL	Health based screening level	ug/l	microgram per liter
MDL	Method detection level	USEPA	Environmental Protection Agency
ng/l	nanogram per liter	USGS	United States Geological Society
PPCP	Pharmaceuticals and personal care products		

A word about units

Analytical data are reported in units of mass per volume - nanograms per liter (ng/l), and in some instances, micrograms per liter (ug/l).

so: 1 ng/l x 1 ug/1,000 ng = 0.001

1,000 micrograms equal 1

so: 1 ug/l x 1 mg/1,000 ug = 0.001

1,000,000 nanograms equal l

so: 1 ng x 1 mg/1,000,000 ng = 0.000001 mg

ng/l ~ ppt, parts per trillion

ug/ l ~ ppb, parts per billion

mg/l ~ ppm, parts per million

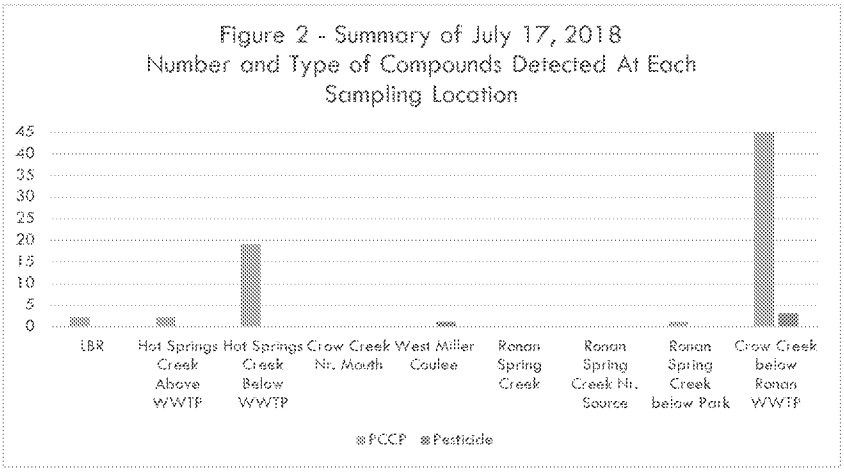
Concentration data reported at nanogram per liter levels are resolved at extremely low concentrations, reflecting advances in analytical procedures and analytical equipment. Water quality criteria and health-based and ecological screening levels are reported at order of magnitude higher levels - ug/l and/or mg/l.

INTRODUCTION

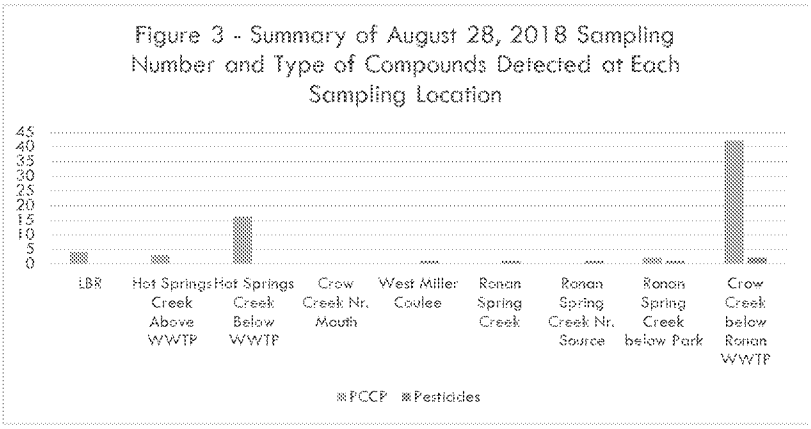
The CSKT Pesticides Program summarizes water quality data collected over the 2018 sample season in this report. Samples were collected in various surface waters, including natural streams, irrigation return flows, and wastewater treatment outfalls. Samples were analyzed for pesticides, pharmaceutical compounds, personal care products, and selected other contaminants of emerging concern.

The Program has collected a well-documented set of data over the last ten years and this report provides an opportunity to characterize data for the last year of record. This information can be used to adaptively review the sampling program, and potentially modify future sampling efforts.

Two rounds of sampling occurred in 2018: July 17th and August 28th respectively. Each round collected a total of 11 samples at 9 sites (see Figure 1 – Map of 2018 Sampling Locations). In July, 8 of the 11 samples representing 5 sites had positive detections for Pharmaceuticals and Personal Care Products (PPCPs) (including the trip blank sample). Two sites showed detections for pesticides and three sites showed non-detections for either pesticides or PCCP's. (Figure 2, Table 1).



In August, five of the eleven samples representing four sites had positive detections of PPCPs (including the trip blank sample). One site tested negative for both PPCPs and Pesticides (Crow Creek Near Mouth) and five sites showed detections of pesticides (see Figure 3, Table 2). Not surprisingly, the highest detections for both sampling rounds occurred in samples collected below the City of Hot Springs and City of Ronan wastewater treatment plants.



Two locations (The Little Bitterroot River below Hot Springs Creek and West Miller Coulee) have been sampled every year since 2008. Both sites had detections in prior years of sampling. In 2018, both sites had detections. Crow Creek near the mouth has been sampled thirteen times since 2008, with positive detections in twelve events. No compounds were detected at this site in 2018. The Ronan WWTP outfall routinely has the highest number of detected compounds. In 2018, an average of 43.5 compounds were detected- primarily pharmaceuticals. Over the counter, prescription, opioid pain medication, and psychostimulant drugs were also detected. A similar pattern was observed in the Hot Springs WWTP outfall. The most commonly detected analytes in both July and August were DEET and Gabapentin. Sample results for each site will be described in detail later in this report.

Table 1 – Summary of Compounds Detected at Each Sampling Site on July 17, 2018.

Detected Compound	Use	Unit	Reporting Limit	LBR Trip Blank	LBR Sample	LBR Duplicate	Hot Springs Creek Above WWTP	Hot Springs Creek Below WWTP	Crow Creek Near Mouth	West Miller Coulee	Ronan Spring Creek	Ronan Spring Creek Near Source	Ronan Spring Creek Below Town Park	Crow Creek Below WWTP
10,11-dihydro-10-hydroxycarb amazepine	antiseizure metabolite	ng/L	10					31						45.5
Acetaminophen	pain killer	ng/L	10											10.9
Bupropion	antidepressant	ng/L	10											24.8
Caffeine	stimulant	ng/L	10				16.7	11.6						13.9
Carbamazepine	anticonvulsant	ng/L	10					13.5						122
Carisoprodol	muscle relaxant	ng/L	10											20.3
DEET	insecticide	ng/L	10	23.8	12.3	11.6	87.7	48.1					22.1	66.7
Desmethylvenlafaxine	antidepressant	ng/L	10					14.6						412
Dextrorphan	cough suppressant	ng/L	10					17.5						60.6
Diphenhydramine	antihistamine	ng/L	10											18.3
Fluconazole	antifungal	ng/L	10					11.7						84.4
Gabapentin	anticonvulsant	ng/L	10		12.8	14.1		367						1850
Gemfibrozil	cholesterol treatment	ng/L	10					56.7						178
Hydrochlorothiazide	blood pressure	ng/L	10											25.6
Hydroxybupropion	antidepressant metabolite	ng/L	10					22.7						110
Lamotrigine	anticonvulsant	ng/L	10					92.1						562
Lidocaine	anesthetic	ng/L	10											96.8
Meprobamate	anti anxiety	ng/L	10											48.4
Metaxalone	muscle relaxant	ng/L	10											104
Metformin	diabetes	ng/L	10					49						18.8
Methamphetamine	stimulant	ng/L	10											38.9
Methylparaben	cosmetic fixative	ng/L	10	21.6										
Metoprolol	blood pressure	ng/L	10					10.2						29.5
Monoethylglycinexylidide	lidocaine metabolite	ng/L	10											35.4
Norfentanyl	fentanyl metabolite	ng/L	10											10.2
Norquetiapine	antidepressant	ng/L	10											11.1
Oxcarbazepine	anticonvulsant	ng/L	10											41.6
Phenobarbital	antiseizure metabolite	ng/L	10											17.8
Phenytoin	antiseizure metabolite	ng/L	25											125
Pregabalin	neuropathic pain	ng/L	10					11.9						191
Primidone	antiseizure	ng/L	10					25.8						18.2
Pseudoephedrine	stimulant, methamphetamine base	ng/L	10											15
Ritalinic acid	psychostimulant metabolite	ng/L	10											46.4
Sotalol	heart rhythm medication	ng/L	10											60.2
Sulfamethazine	antibiotic (livestock)	ng/L	10											11.6
Sulfamethoxazole	antibiotic (livestock)	ng/L	10					22.6						14.1
Temazepam	insomnia	ng/L	10											31.7
Tramadol	opiod pain medication	ng/L	10					21.2						247
Triamterene	diuretic	ng/L	10					10.9						13.2
Valsartan	blood pressure	ng/L	10											26.2
Venlafaxine	antidepressant	ng/L	10					11.2						11.2
Warfarin	blood thinner	ng/L	10											10.2
Zolpidem phenyl-4-carboxylic acid	insomnia	ng/L	10											10.9
Diuron	algicide/herbicide	ng/L	20											32.1
MCPP	herbicide	ng/L	20											36.4
Prometon	herbicide	ng/L	20											44.9
2-4 D	herbicide	ng/L	10							60.9				

Table 2 - Summary of Compounds Detected at Each Sampling Site on August 28, 2018

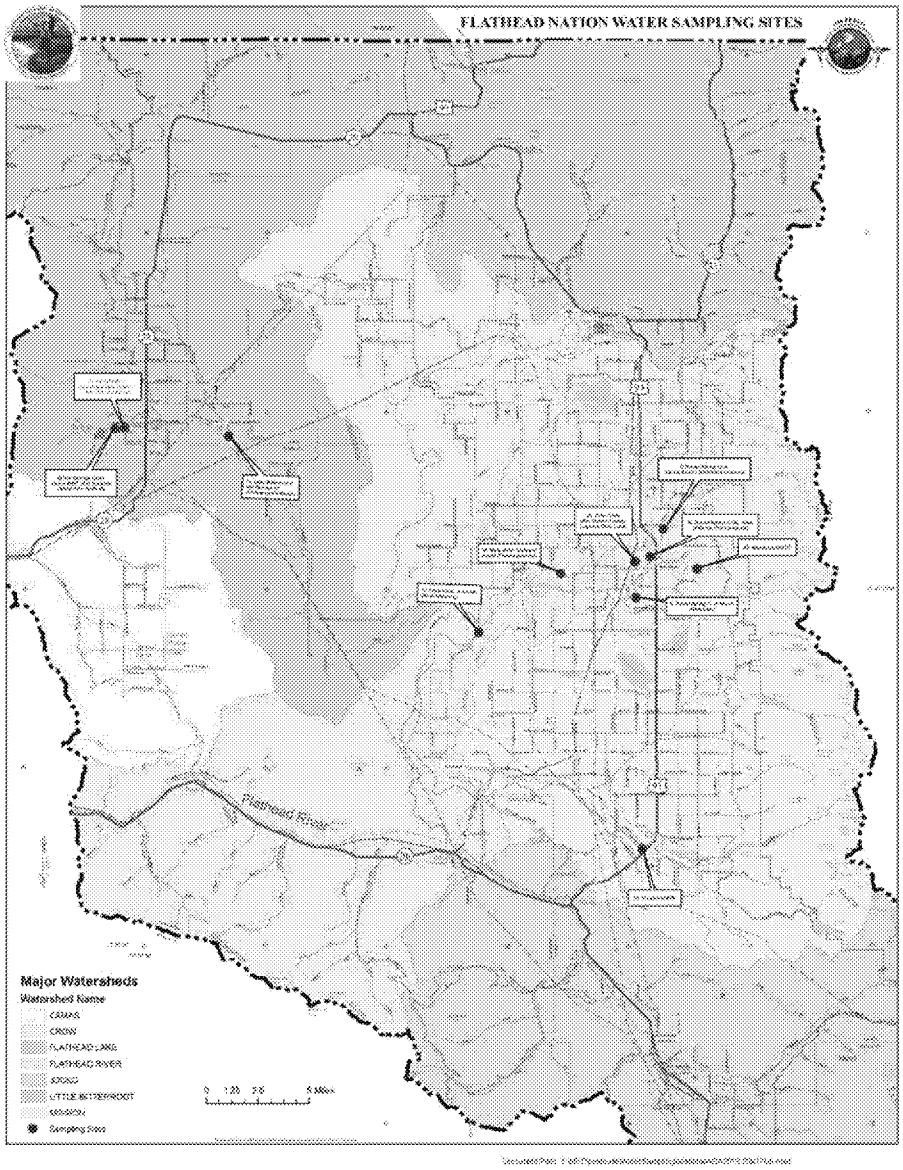
Detected Compound	Use	Unit	Reporting Limit	LBR Trip Blank	LBR Sample	LBR Duplicate	Hot Springs Creek Above WWTP	Hot Springs Creek Below WWTP	Crow Creek Near Mouth	West Miller Coulee	Ronan Spring Creek	Ronan Spring Creek Near Source	Ronan Spring Creek Below Town Park	Crow Creek Below WWTP
10,11-dihydro-10-hydroxycarb amazepine	antiseizure metabolite	ng/L	10					20.9						231
Acebutolol	pain killer	ng/L	10											10.8
Acetaminophen	antidpressant	ng/L	10											20.8
Bupropion	stimulant	ng/L	10				31.5	12.3						44.8
Caffeine	stimulant	ng/L	10	26.6									13.1	
Carbamazepine	anticonvulsant	ng/L	10					13.6						284
Carisoprodol	muscle relaxant	ng/L	10											51.3
DEET	insecticide	ng/L	10	52.3		23.8	56.9	24.5						130
Desmethylvenlafaxine	antidepressant	ng/L	10					11.2					32.9	972
Dextrorphan	cough suppressant	ng/L	10											75.7
Diphenhydramine	antihistamine	ng/L	10											25.8
Fluconazole	antifungal	ng/L	10											104
Gabapentin	anticonvulsant	ng/L	10					308						3040
Gemfibrozil	cholesterol treatment	ng/L	10					42.2						437
Hydrochlorothiazide	blood pressure	ng/L	10											53.2
Hydroxybupropion	antidepressant metabolite	ng/L	10					32.9						262
Ibuprofen	pain killer	ng/L	10											41.2
Lamotrigine	anticonvulsant	ng/L	10					297						1550
Lidocaine	anesthetic	ng/L	10					14.3						273
Lorazepam	insomnia	ng/L	10											11.2
Meprobamate	antianxienty	ng/L	10											154
Metaxalone	muscle relaxant	ng/L	10											154
Metformin	diabetes	ng/L	10		11.9	11.8	15.2	40.9						15.7
Methamphetamine	stimulant	ng/L	10					14.1						99.6
Methylparaben	cosmetic fixative	ng/L	10	21.6										
Metoprolol	blood pressure	ng/L	10											119
Monoethylglycinexylidide	lidocaine metabolite	ng/L	10					10.1						112
Norfentanyl	fentanyl metabolite	ng/L	10											14.6
Norquetiapine	antidepressant	ng/L	10											16.1
Oxazepam	anticonvulsant	ng/L	10											12.4
Oxcarbazepine	anticonvulsant	ng/L	25											201
Phenobarbital	antiseizure metabolite	ng/L	10											12.6
Phentermine	weight loss	ng/L	10											68.1
Phenytoin	antiseizure metabolite	ng/L	10											582
Pregabalin	neuropathic pain	ng/L	10											407
Primidone	antiseizure metabolite	ng/L	10					28.9						34.2
Pseudoephedrine	stimulant, methamphetamine base	ng/L	10											22.4
Ritalinic acid	psychostimulant	ng/L	10											90.9
Sotalol	heart rhythm medication	ng/L	10											180
Sulfamethazine	antibiotic (livestock	ng/L	10					21.2						50
Sulfamethoxazole	antibiotic (livestock	ng/L	10					25.4						
Temazepam	insomnia	ng/L	10											39.2
Tramadol	opiod pain medication	ng/L	10											454
Triamterene	diuretic	ng/L	10					13.3						10.7
Valsartan	blood pressure	ng/L	10											116
		ng/L	10											10.9
Diuron	algicide/herbicide	ng/L	20											32.9
MCPP	herbicide	ng/L	20											
Prometon	herbicide	ng/L	20											39.8
Metolachlor	herbicide		20									27.1	22.3	
2,4-D	herbicide	ng/L	20							44.3	31.7			

In no instance did concentrations of any one compound approach a water quality standard criterion or health-based screening level. Certain of the detected compounds, for example the herbicide diuron has been shown to have adverse effects to aquatic life at environmental concentrations of 170 ug/L (Fojut 2010). Diuron concentrations were measured at 32.1 ng/L in July and 32.9 ng/L in August at the RWWTP outfall.

Report format

This report is formatted with a body of text and a compilation of figures and tables embedded within the report. The tables contain extensive detail on the results of the sampling program, including a location-by-location summary for the 2018 sample event. Much of the information found in the tables and figures is not described in the body of the report, and these should be directly reviewed for detail.

Figure 1 – Map of Pesticide Program Sampling Locations 2018



SECTION 1 – 2018 PESTICIDES PROGRAM SAMPLING

Background and Objectives

Analytical results of water samples tested for pesticides, pharmaceutical, and personal care products (PPCPs), and other contaminants of emerging concern (CEC's) are available for various years from 2008 through 2017 at stream, irrigation return flow, and wastewater treatment plant (WWTP) outfall sites in watersheds across the Flathead Indian Reservation.

As part of this ongoing effort, sampling and reporting was completed by the Confederated Salish and Kootenai Tribes (CSKT) Division of Environmental Protection, Pesticides Program (Program) in 2018. The Program completed sampling at nine locations on August 28, 2018.

Work was supported through Region 8 U.S. Environmental Protection Agency (EPA) awards to the CSKT Pesticides Program.

Sampling in 2018 was completed following an approved Sampling and Analysis Plan and Quality Assurance Quality Control Project Plan (QAPP) with the objective to:

1. Document the presence or absence of pesticides, PPCPs, and other contaminants of emerging concern in various surface waters across the Reservation;
2. Document concentration levels and benchmark these to human health and/or ecological criteria, where available;
3. Sample WWTP outfalls, based on prior-year detections of CEC's in natural streams downstream of treatment outfalls;
4. Continue the year-to-year dataset to look for patterns at and between locations; and
5. Provide a quality-assured dataset that may be used for pesticides and water quality management.

Pesticides pharmaceuticals, and personal care products along with their respective degradate compounds were sampled for in 2018. Since 2013, sampling efforts have focused on locations with a record of detections. Sampling in 2018 included the outfalls from the Ronan and Hot Springs wastewater treatment plants.

Data quality objectives for 2018 sampling add to;

1. A dataset of known quality, with both field and analytical lab quality assurance documentation;
2. A representative dataset for the time period bordering the sample; and
3. A dataset that is comparable across sampling events for sampling methods, analytical methods, and site location.

The 2018 sampling event was completed by the CSKT and samples were processed by the EPA Region 8 analytical lab. The EPA lab reports compound concentrations at the nanograms per liter (ng/l) level which is equivalent to parts per trillion (ppt). Field sampling procedures have remained consistent through all years of the project. Analytical methods have remained generally consistent since the EPA lab began work, with minor changes in the analyte schedule and reporting levels between years. Appendix A contains the analytical parameters and reporting levels for 2018.

Tables 1 and 2 report the number of detected analytes for each location sampled in 2018. The table provides a snapshot of sample locations and locations with higher relative detections. Figure 1.0 summarizes the sample locations utilized by the CSKT Pesticides Program in 2018.

Purpose and Scope

This report summarizes the results from two sampling events for pesticides, PPCPs, and other CEC's in streams, irrigation return flows, and wastewater treatment outfalls. Results are summarized to describe the 2018 sampling event, and narrative is added in some portions of the document to indicate trends from prior year's sampling. Classes of compounds are discussed, and data are benchmarked to a health or ecological criterion where information is readily available. Water quality loads are reported for the date of each sampling event. ***The report does not associate detected compounds with specific sources or reach conclusions for regulatory or compliance purposes.***

Discussion

Previous Reporting on Pesticides Sampling

Gaufin (1974) reported detections of DDT and its metabolites in bottom sediments in Flathead Lake. The author also reported occurrences of the pesticides tordon and chlordane in surface and ground water in the Mission Valley. Ericson and Essig (1981), analyzing for a limited suite of pesticides, did not report detections for surface water locations in the Mission Valley. Jourdonnais and Stanford (1985) looked at bioaccumulation of organochlorine pesticides in Lower Crow Reservoir. The authors reported P-DDE, a degradate of DDT, in fatty tissues of perch at levels below human health standards at the time. Clark (1990) sampled for the pesticide aldicarb in shallow groundwater wells in a potato field near Ronan. The author reported aldicarb and its metabolites in monitoring wells seven weeks after application.

The vulnerability of mapped aquifers to pesticide occurrence was modeled using a spatial analysis procedure like the EPA DRASTIC method (EPA, 1987; Makepeace and Gilliard, 2001). Several shallow aquifers were identified as having pathways for pesticides migration to groundwater. The Tribal Fisheries Program (personal communication) sampled fish tissue for pesticides and pesticide degradates in Kicking Horse and Lower Crow Reservoirs in 2001 and 2002. In 2002, degradates of the currently not registered for use organochlorine pesticides – lindane, DDT, and dieldrin, were reported in fish tissue in Lower Crow Reservoir. Core samples were collected in Lower Crow Reservoir (Tetra Tech, 2017) to look for organochlorine pesticides that may have partitioned to reservoir bed sediments; no detections were observed.

The Montana Department of Agriculture MDAG (2008), reporting on a comprehensive state-wide groundwater monitoring effort, detected forty-five separate pesticide compounds, with all state-wide detections below fifty percent of the relevant human health criteria. MDAG maintains a permanent groundwater monitoring network with three wells located on the Reservation, one in an orchard

area on the east shore of Flathead Lake, one in an agricultural area north of Ronan (Clark, 1990), and one in an agricultural area in the Moiese Valley. All three MDAG wells had detections of atrazine or atrazine degradates, simazine and prometon. Atrazine is listed for application on both corn and orchard crops.

Prometon is a non-selective herbicide used for total vegetation control. It is very persistent (high half-life) and has high potential to migrate into groundwater. Simazine is a non-selective herbicide. MDAG (2016) reports that atrazine and degradates and prometon continued to be found at low levels in Reservation wells in the permanent groundwater network. MDAG initiated a targeted study on the east shore of Flathead Lake (MDAG, 2010). The insecticide imidacloprid, used to control cherry fruit flies, was detected in two surface water springs but not in groundwater wells. Atrazine and atrazine degradates were detected in domestic groundwater wells, with persistent detections in one bedrock well finished at 90 feet. General use herbicides (2,4-D and MCPA) were also detected in domestic wells and springs. In all instances, detections were well below human health criteria.

The CSKT Pesticides Program reported on 2008 through 2014 sampling events (CSKT; 2010 2011a and b, 2013, 2015). The Program found low concentrations of pesticides at one or more times in several surface waters. These data are summarized in prior year reports.

Combined, previous sample sets show that low concentration levels of pesticides have been intermittently observed in valley-floor stream networks across the Reservation.

Compound Classes Reported

Currently used pesticides include herbicides, insecticides, and fungicides that are applied in agricultural areas, in road rights-of-way, and in residential and commercial areas. Currently used pesticides are reported individually, and as cumulative concentrations, since mixtures of pesticides can have synergistic detrimental effects to aquatic species (Laetz et al., 2009). Legacy pesticides, generally organochlorine pesticides that are no longer registered for use, were not

part of the 2018 analytical schedule. The 2018 schedule included seventy-two pesticides or degradates (Appendix A).

Pharmaceutical compounds are widely observed in surface and ground water across the globe (WHO, 2011). They are discharged through treated or untreated wastewater treatment plant outflows, and more diffusely, through onsite septic systems and veterinary medical uses. In 2018, one hundred-forty-one pharmaceutical compounds were included in the analytical schedule (Appendix A).

Pharmaceutical compounds and their degradate products are designed to be biologically active, and as such, generally have low persistence in the environment. However, due to pervasive human use, the term "pseudo-persistence" is applied to indicate that pharmaceutical compounds are continuously input into the environment. The effects of continuous low-level exposure to aquatic life is poorly understood, as are the cumulative effects of mixtures. Since pharmaceuticals are intended to be biologically active, adverse effects would be anticipated, especially to sensitive aquatic life stages (Daughton and Ternes, 1999).

Anthropogenic organic waste compounds include a wide range of compounds associated with human activities. They include personal care products, fragrances and detergents and their metabolites, plasticizers, flame retardants and numerous organic compounds. Polycyclic aromatic compounds (PAH's) are widespread persistent organic contaminants that are found in paints, creosotes, and petroleum products. One widespread source of PAH's are road surface sealcoats. PAH's may be found in treatment plant discharges but are also common constituents in storm water runoff. PAH's readily partition to sediments, increasing their retention time in the environment. Certain PAH's are also recognized or suspected carcinogens for vertebrate species (Morace, 2012).

For the 2018 sampling event, whole water samples were collected in surface waters. Samples were analyzed to detect the presence or absence of pharmaceuticals, personal care products, and pesticides. Several classes of pesticides and CEC's are known to partition to sediment and soil matrices; compounds sorbed to solids are not represented in the sample sets.

Hydrologic Conditions During the 2018 Sampling Events

Hydrologic and meteorological conditions, in this application streamflow and precipitation, are one explanatory variable for the types of compounds observed in the dataset and their concentration levels.

The representativeness of a sampling event – its applicability over a longer-time period, can also partially be inferred from streamflow and precipitation patterns bordering each event.

Higher overall soil moisture and subsoil water amounts increase the extent of saturated flow connection in stream networks, potentially increasing the rate of compound transport from source to receiving stream.

Irrigation return flow and WWTP outfall flow volumes may be less influenced by antecedent hydrologic conditions, and more influenced by near-term events – precipitation prior to sampling events, irrigation water management, and residential and commercial use patterns.

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The representativeness of a sampling event – its applicability over a longer-time period, can also partially be inferred from streamflow and precipitation patterns bordering each event.

Seasonal streamflow levels often mirror soil moisture content and groundwater levels, with higher streamflow levels coincident with higher overall subsurface moisture levels. Higher overall soil moisture and subsoil water amounts increase the extent of saturated flow connection in stream networks, potentially increasing the rate of compound transport from source to receiving stream.

Irrigation return flow and WWTP outfall flow volumes may be less influenced by antecedent hydrologic conditions, and more influenced by near-term events –

precipitation prior to sampling events, irrigation water management, and residential and commercial use patterns.

Pesticides, especially herbicides, are applied earlier in the summer season during the plant emergence period, and this likely contributed to higher observed concentrations in July during prior year sampling events. Samples were collected in August in 2018 which may account for the comparably lower observed concentrations. Wastewater treatment plant outfalls have been sampled for the past 3 years. Given the low sample number, it is difficult to determine trends at this time. Further, the City of Ronan is in the process of upgrading its treatment plant and wetland polishing beds which will likely affect data in the future.

Hydrologic conditions are one contributing factor for pesticides and PPCP detections. With pesticides - application timing, irrigation practice - on farm and canal return flow runoff, and emergence times of weed and pest targets all influence pesticide use. Anthropogenic waste compounds detections are often correlated to storm water runoff and human use patterns, which are likely to be consistent over time.

SECTION TWO: SAMPLING AND ANALYSIS PROCEDURES AND QUALITY ASSURANCE

Reporting Data

Analytical results for compounds are reported as detected or not detected in the EPA lab reports. Detected compounds are reported as the concentration measured. Data are qualified as estimated if there are discrepancies in the chain-of-custody, if there are performance issues with the analytical procedures, or if there are interference issues between analytes or between analytes and the sample matrix. This information is documented through the lab quality control samples found in the lab reports. When data are not detected, the results are reported as a value less than the reporting limit (RL). These data are often termed censored (Helsel and Hirsh, 2002). Data that are reported as not detected does not indicate the

compound is not present, since it may be present in the sample matrix at concentrations below the reporting limit.

Method detections limits (MDL's) are not reported for analytical procedures in the EPA lab reports, but there may be instances where a compound is reported as detected with an estimated qualifier, if the compound is determined present at a concentration between the RL and the MDL. Method detection limits are defined as the minimum concentration of a compound that can be measured with a ninety-nine percent confidence that the analyte concentration is greater than zero. Alternatively, there is a less than one percent chance that an analyte concentration was reported, but the analyte was not present (false positive).

Throughout this memo, data are reported in nanograms per liter (ng/l), which at reference water temperature conditions equates to parts per trillion (ppt).

Sampling and Analysis procedures

In 2018 whole water samples (unfiltered) were collected following a grab sample procedure, with samples collected in well mixed cells of the stream cross section. Sampling followed the procedures found in the Program's QAPP. Samples were maintained on ice and delivered to the EPA Region 8 lab under chain-of-custody. Samples were analyzed for a suite of pesticides and pesticide degradates and pharmaceutical and personal care products following Region 8 Standard Operating procedures SOP ORGM-550, SOP ORGM-006 and SOP ORGM-001. Pharmaceuticals and personal care products were analyzed using EPA method 1694 and pesticides were analyzed using a Region 8 pesticides procedure by LC/MS/MS.

Field chemistry and streamflow discharge information were collected following the CSKT Water Quality Program QAPP. Reporting levels for field parameters are found in Table 3.0.

Quality Assurance

Replicate and field blank quality control samples were submitted with each event. The EPA analytical lab documented quality assurance using blanks, matrix spikes,

lab duplicates and equipment calibration results. Quality assurance results are documented in the lab reports and a data qualifier (estimated data) was applied for data outside of lab QC criteria.

Replicate field samples were collected consecutively following the same sample collection and processing steps. Replicate samples test for precision, which is a measure of the variability of lab processing methods and measurement precision. Relative percent difference (RPD) is calculated as:

$$\text{Relative Percent Difference (value z)} = \frac{((\text{value 1} - t))}{\text{value 1} + \text{value 2})/2} \times 100$$

where, RPD is the absolute difference between two samples normalized to the average of the two values and reported as a percentage. Lower RPD values indicate closer agreement between the analytical results. The Water Quality and Pesticides Program have traditionally used 25% as a threshold to identify replicate samples outside of quality control criteria. Recognizing that the lab results are reported at extremely low levels (ng/l), this RPD value may be too stringent for these data. For this report, analytes reported with higher RPD levels in quality control samples and reported as detected in environmental samples, are treated as detections.

Field blanks are contaminant-free water that is processed and handled in the same way as field samples. Field blanks are used to assess field interference issues arising from sample processing, handling and transport. Various approaches have been employed to utilize analytical results for field samples reported as detected in field blanks (see for example Morace, 2012). Analyte detections for field blanks were limited in number, and results are reported at the observed concentration for compounds that were detected in both field blanks and environmental samples.

Quality Assurance for the 2018 sampling events

The chain-of-custody found in the analytical lab report for the July 17 and August 28, 2018 events indicates that samples were received by the lab in good condition. The lab did note that all samples received by the EPA lab in July arrived at the

laboratory above the temperature requirement (samples were 22 ^{0}C). As a result, all results were qualified as estimated results.

Relative percent difference for replicate samples is reported in Table 4.0. Three analytes were detected at low levels in the field blanks – Methylparaben, DEET and caffeine. A very limited number of analytes were reported as estimated by the lab, based on their quality control analytical results. Quality assurance issues were not identified for this sampling event.

Quality Assurance Summary

CSKT (2012) includes an in-depth discussion of the comparability between sampling events for each year up to that date. Field sampling procedures have remained consistent and are comparable between years. Analytical methods have remained consistent over the period when the EPA lab has analyzing samples.

Quality control criteria were not met for certain analytes in each sampling event. Year to year QC results do not exhibit a trend or outliers relative to each other. Since data are used for descriptive and trends purposes, rather than regulatory purposes, analytical results were accepted, and compounds detections are reported at the lab-reported concentration value.

SECTION THREE: SUMMARY OF 2018 DATA

Full results for the analytical sample schedule, including detected and non-detected analytes and lab quality control, are found in the analytical lab reports maintained with project files. Below, concentrations for detected pesticides and PPCP's are discussed.

July 17, 2018 sampling event

Analytical data for the July 2018 sampling event follows patterns observed since sampling of WWTP outfalls began in 2008. Analysis results indicated elevated

pharmaceutical concentrations and detected compounds below the Ronan WWTP, and fewer detections below the Hot Springs WWTP. Pesticide concentrations were very low, with detections only observed at West Miller Coulee, and the Ronan WWTP outfall.

Pharmaceutical compounds were observed at 5 of the 9 sample locations. No pharmaceuticals, personal care products or pesticides were found at the Crow Creek near Mouth site. This is notable, since Crow Creek is the receiving water for discharge from the Ronan WWTP. Low concentrations of Gabapentin, an anticonvulsant medication was observed in the Little Bitterroot River, Hot Springs Creek below the WWTP and Crow Creek below the WWTP. Gabapentin has been widely observed, and in the July 2018 event, accounted for 37.8% of the cumulative concentration below the Ronan WWTP.

August 28, 2018 sampling event

Analytical data for the August 2018 sampling event closely tracked patterns observed in July. Analysis results indicated elevated pharmaceutical concentrations and detected compounds below the Ronan WWTP, and fewer detections below the Hot Springs WWTP. Pesticide concentrations were very low, with detections observed at West Miller Coulee, Ronan Spring Creek, Ronan Spring Creek near the source, Ronan Spring Creek below the City Park, and the Ronan WWTP outfall.

Pharmaceutical compounds were observed at 4 of the 9 sample locations. No pharmaceuticals, personal care products or pesticides were found at the Crow Creek near Mouth site. As in July, low concentrations of Gabapentin were observed in the Little Bitterroot River, Hot Springs Creek below the WWTP and Crow Creek below the WWTP. In the August 2018 event, Gabapentin accounted for 29% of the cumulative concentration below the Ronan WWTP.

Cumulative concentrations across all sample locations during both events were low, with the highest cumulative concentration and number of detections found at Crow Creek below the Ronan WWTP sample site. In August, Crow Creek Near Mouth, West Miller Coulee, Ronan Spring Creek and Ronan Spring Creek near Source had

zero detections of PCCPs. Only two sample locations, West Miller Coulee and Crow Creek at Mink Lane located below the Ronan WWTP had detections of pesticides. Unlike prior years, the herbicide 2,4-D was detected at only one site -West Miller Coulee. Diuron and Prometon were detected at Crow Creek at Mink Lane. DEET was found in 6 of the 11 samples.

Water quality load estimates

Water quality loads are reported for the 2018 sampling event in Table 12.0. Water quality loads are estimated by combining concentration and discharge and correcting for unit conversions. Load, in the current application, is estimated as:

$$Load = k * Conc * Q$$

Load is the water quality load reported in pounds/day (lb/d),

k is a conversion factor to convert concentration in ng/l and discharge in ft^3/s to load in lb/d (0.00000539),

Conc is the reported concentration in ng/l, and Q is the field-measured discharge in ft^3/s.

Water quality loads are reported in time units of days; this assumes that the point-in-time discharge and concentration data are representative over a full day. Reporting in time units of days was done because instantaneous loads, reported in time units of seconds, are extremely low and difficult to compare across stations. The assumption of stable flows over a day is generally appropriate and should not influence comparison between sampling locations. Loads were not extrapolated beyond one day, since both concentration and discharge likely vary.

Water quality loads recast concentration data in terms of a mass per time loading rate. Additionally, concentration data are normalized to discharge, and this allows direct comparison of mass loading rates between locations. Water quality loads are often reported in time units of years, for example tons per year. The Program sample collection interval is too infrequent to permit reporting over longer time frames. Further, the detection patterns suggest that concentrations of specific analytes, especially pesticides, are event-related and difficult to project beyond a specific sampling event.

Loads estimates are summarized for each detected analyte for each sample site in the following section. Data indicate that, in all instances, observed loads are low. The highest individual load was observed in West Miller Coulee, and equaled 0.177 lb/d for all analytes. Analyte concentrations were highest in the Ronan wastewater treatment outfall, and the estimated load was highest at this location for the final two sample events. However, due to the low discharge volumes, the total load in the WWTP outfall was low. Low mass inputs likely contribute to much lower detections of PPCP's in receiving waters downstream of the WWTP's – Crow Creek and the Little Bitterroot River.

SECTION FOUR: SUMMARY OF 2018 DATA

Table 5 summarizes the results of each analyzed sample at each site for each of the sampled locations; cumulative concentrations are reported by analytical procedure.

The Little Bitterroot River below Hot Springs Creek, West Miller Coulee, and Crow Creek below the Ronan WWTP have been sampled >10 times since 2008. Other locations have variable periods of record.

Tables 1 and 2 summarize overall detections for the 2018 sampling event.

In 2018 fifty-one percent of samples indicated positive detections and forty-nine percent of samples had non-detections. This is a reduction in positive detections when compared to the 2015 through 2017 period, where seventy-two percent of samples had positive detections.

Site by site summary of analysis

In this section, each sample site is summarized to highlight past sample trends as well as the data collected in the most recent year. Sites will be described in the order that samples were collected on August 28, 2018 (see Chain of Custody – Figures. 4 and 5.

Little Bitterroot River Below Hot Springs Creek

Sampling has been completed at this location during each event from 2008 through 2018. One or more analytes has been detected in twelve of the thirteen sample sets. In prior years, the most widely detected analyte was Gabapentin, an anticonvulsant medicine; this was followed by the herbicide 2,4-D, and the diabetes medicine Metformin. Cumulative concentrations were low, and in no instance exceeded 337 ng/l.

PPCP Analysis

In 2018 three samples were collected at this site. The July samples showed detections of DEET and Gabapentin with the concentration of DEET being the highest in the trip blank sample. Cumulative concentrations totaled 74.6 ng/L.

PPCPs detected in Little Bitterroot River Samples collected July 17, 2018

Sample Number	Parameter	Result	Unit	Report Limit	Load	Percent Concentration
12	DEET	12.3	ng/L	10	0.000908	16.48793566
	Gabapentin	12.8	ng/L	10	0.000945	17.15817694
12 Blank	DEET	23.8	ng/L	10	0.001757	31.90348525
12 Duplicate	DEET	11.6	ng/L	10	0.000857	15.54959786
	Gabapentin	14.1	ng/L	10	0.001041	18.90080429

In August, the trip blank showed detections of caffeine, DEET, and methylparaben (a preservative often added to food and cosmetics to prolong shelf life). Sample 12B and the trip duplicate sample both contained Metformin. DEET was present in the trip blank and the duplicate samples. Cumulative concentrations for all three samples totaled 148 ng/L. The presumption is that these compounds are introduced into the Little Bitterroot River from Hot Springs Creek.

No Pesticides were detected in the trip blank, sample, or duplicate sample collected at the Little Bitterroot River site in July or August.

PPCPs detected in Little Bitterroot River Samples collected August 28, 2018

Sample Number	Parameter	Results	Units	Report Limit	Total Load (lb/day)	Percent Concentration
12 A Blank	Caffeine	26.6	ng/L	10	0.002	66.85
	DEET	52.3	ng/L	10	0.0009	33.14
	Methylparaben	21.6	ng/L	10	0.0009	33.14
12	Metformin	11.9	ng/L	10	0.001	33.42
12 Duplicate	DEET	23.8	ng/L	10	0.002	66.85
	Metformin	11.8	ng/L	10	0.0009	33.14

Hot Springs Creek Upstream and Downstream of the WWTP

Samples were collected in Hot Springs Creek above and below the WWTP in 2018. These sample locations were added following recurrent observation of pharmaceutical compounds in the Little Bitterroot River downstream of the confluence with Hot Springs Creek. The upstream site is in the town of Hot Springs and stream chemistry may be influenced by storm-water outfalls and nonpoint source inputs.

The upstream site detected Caffeine and Deet in July with a total concentration of 104.4 ng/L. In August, sample composition was similar but also included a very low concentration of metformin. Total concentration of detected analytes in August was 103.6 ng/L.

No pesticides were detected in either sample event at this site.

PPCPs detected in Hot Springs Creek Above WWTP samples collected July 17, 2018

Sample Number	Parameter	Result	Units	Report Limit	Load	Percent Concentration
22	**Caffeine**	**16.7**	ng/L	10	0.00018	15.99616858
	DEET	**87.7**	ng/L	10	0.0009454	84.00383142

PPCPs detected in Hot Springs Creek Above WWTP samples collected August 28, 2018

Sample Number	Parameter	Results	Units	Report Limit	Total Load	Percent Concentration
22	**Caffeine**	**31.5**	ng/L	10	0.00014	30.4
	DEET	**56.9**	ng/L	10	0.00027	54.9
	Metformin	**15.2**	ng/L	10	0.00007	14.6

In July, 19 separate pharmaceutical compounds, including psychostimulant drugs, were detected in Hot Springs Creek downstream of the WWTP. One pesticide, DEET, was detected. Gapapentin was present in the highest concentration (367 ng/L) even though total concentrations were low overall (849 ng/L).

PPCPs Detected Below Hot Springs Creek July 17, 2018

Sample Number	Parameter	Results	Unit	Report Limit	Total Load (lb/day)	Percent Concentration
21	10,11-dihydro-10-hydroxycarb amazepine	31	ng/L	10	0.000012164	3.650064759
	Caffeine	11.6	ng/L	10	0.000004552	1.365830684
	Carbamazepine	13.5	ng/L	10	0.000005297	1.589544331
	DEET	48.1	ng/L	10	0.000018874	5.663487578
	Desmethylvenlafaxine	14.6	ng/L	10	0.000005729	1.719062758
	Dextrorphan	17.5	ng/L	10	0.000006867	2.060520429
	Fluconazole	11.7	ng/L	10	0.000004591	1.377605087
	Gabapentin	367	ng/L	10	0.000144008	43.21205699
	Gemfibrozil	56.7	ng/L	10	0.000022249	6.676086189
	Hydroxybupropion	22.7	ng/L	10	0.000008907	2.672789356
	Lamotrigine	92.1	ng/L	10	0.000036139	10.84422466
	Metformin	49	ng/L	10	0.000019227	5.7694572
	Metoprolol	10.2	ng/L	10	0.000004002	1.20098905
	Pregabalin	11.9	ng/L	10	0.000004669	1.401153891
	Primidone	25.8	ng/L	10	0.000010124	3.037795832
	Sulfamethoxazole	22.6	ng/L	10	0.000008868	2.661014953
	Tramadol	21.2	ng/L	10	0.000008319	2.496173319
	Triamterene	10.9	ng/L	10	0.000004277	1.283409867
	Venlafaxine	11.2	ng/L	10	0.000004395	1.318733074

In August, sixteen compounds were detected below the WWTP. Unlike the July event, Triamterene (a diuretic) and Venlafaxine (an antidepressant) were not detected in the August sample. The difference in the August sample indicates the high degree of resolution in the laboratory analytical procedures. Total loads for both sites above and below the WWTP were very low (averaging 0.002 ng/L). No pesticides were detected in either the upstream or downstream samples collected at Hot Springs Creek.

PPCPs detected in Hot Springs Creek Below WWTP samples collected August 28, 2018

Sample Number	Parameter	Results	Units	Report Limit	Total Load	Percent Concentration
21	10-11-dihydro-10-hydroxycarbamazepine	20.9	ng/L	10	0.00004269	2.331808546
	Caffeine	12.3	ng/L	10	0.00002513	1.372308379
	Cabamazepine	13.6	ng/L	10	0.00002778	1.517349102
	DEET	24.5	ng/L	10	0.00005005	2.733459779
	Desmethylvenlafaxin	11.2	ng/L	10	0.00002288	1.249581613
	Gabapentin	308	ng/L	10	0.00062919	34.36349437
	Gemfibrozil	42.2	ng/L	10	0.00008621	4.708245007
	Hydroxybupropion	32.9	ng/L	10	0.00006721	3.670645989
	Lamotrigine	297	ng/L	10	0.00060671	33.13622671
	Lidocaine	14.3	ng/L	10	0.00002921	1.595447953
	Metformin	40.9	ng/L	10	0.00008355	4.563204284
	Methamphetamine	14.1	ng/L	10	0.00002880	1.573133995
	Monoethylglycinexyli	10.1	ng/L	10	0.00002063	1.126854848
	Primidone	28.9	ng/L	10	0.00005904	3.224366841
	Sulfamethoxazole	25.4	ng/L	10	0.00005189	2.833872587
	Tramadol	13.3	ng/L	10	0.00002717	1.483878166

Crow Creek below Lower Crow Reservoir (River Honoring Site)

Lower Crow Creek is the receiving water for a large valley-floor land area with irrigated and dryland agriculture, light industrial and commercial use and the communities of Pablo and Ronan. The downstream sampling location is located

below lower Crow Reservoir and above the confluence with the Flathead River. There were no PPCPs detected in either the July or August 2018 sampling event. No Pesticides were detected in the samples collected at this site.

West Miller Coulee

West Miller Coulee is a valley-floor watershed which drains irrigated and dryland agricultural lands. The coulee is tributary to Mud Creek, upstream of lower Crow Reservoir. West Miller Coulee has been sampled in each event over the 2008 through 2017 period. In prior years, several pesticides have been observed, with 2,4-D the most common. In 2018, no PPCP's were detected in the sample collected at this site. 2,4-D was detected in the July sample with a concentration of 60.9 ng/L. In August, 2,4-D was the only compound detected with a concentration of 44.5 ng/L. The total load of 2,-4D for both sampling events was very low (.004 lb/day).

Commented [A1]: Jasmine- I did not create a separate table for West Miller Coulee since there was only one detected compound. I gave its full description in the narrative.

Ronan Spring Creek upstream and downstream

Since 2011, samples have been collected at an upstream location in Ronan, but still within the footprint of the townsite, and downstream at the lowermost access point on the creek. Sampling occurred six times over the full period at the upstream location. Very few detections were observed, and cumulative concentrations were low. Sampling occurred more frequently at the downstream location in the last decade, and a wider range of compounds were detected, although cumulative concentrations were generally low.

In 2018, there were no detections of PPCPs in the July samples. DEET was detected in low concentrations at the Ronan Spring Creek at the Town Park Site.

Since 2008, the greatest number of waste compounds have been detected at the lower location on Ronan Spring Creek. Further, when tentatively identified compounds were reported, their values were elevated (6/10/14 – 10,389 ng/l). Recall, TIC's are compounds that can be identified by the analytical method, but the

concentration cannot be confirmed without additional testing, in this case running a standard (EPA, 2006). This suggests that AWC's may be elevated in lower Ronan Spring Creek, but that the sampling and analytical approaches have not been designed to fully resolve compound types or concentrations. Ronan Spring Creek is known to receive diffuse storm water inputs, and AWC's are often associated with storm water inflows.

PPCPs Detected Above and Below Ronan Spring Creek July 17, 2018

Sample Number	Parameter	Result	Unit	Reporting Limit	Load (lb/day)	Percent Concentration
9	No Detections		ng/L			
8	No Detections		ng/L			
19	**DEET**	**22.1**	ng/L	10	0.001632	100

In August, pesticides were detected at all three sample sites. Caffeine and DEET were also observed in the Town Park site. Total loads at all sites were extremely low (0.007 ng/L). One pesticide, 2.4-D was detected in the upstream sample although its concentration, 11.7 ng/L was barely above the detection limit of 10.0 ng/L. Similarly, one pesticide, Metolachlor ESA was detected at the downstream site at a concentration of 22.3 which is also slightly above the reporting limit of 20 ng/L.

PPCPs Detected Above and Below Ronan Spring Creek August 28, 2018

Sample Number	Parameter	Result	Unit	Reporting Limit	Total Load (lb/day)	Percent Concentration
9	**2,4-D**	**11.7**	ng/L	10	0.001091	100
8	**Metolachlor ESA**	**27.1**	ng/L	20	0.002206	0.370725034
19	**Caffeine**	**13.1**	ng/L	10	0.001066	0.179206566
	DEET	**32.9**	ng/L	10	0.002678	0.450068399
		46				
	Metolachlor ESA	**22.3**	ng/L	20	0.001647	100

Crow Creek Below Ronan WWTP

RONAN WASTEWATER TREATMENT OUTFALL

The Ronan WWTP outfall is a small perennial channel that is tributary to Crow Creek downstream of its confluence with Ronan Spring Creek. The outfall has been sampled since 2016. This site exhibited the highest concentrations and number of detected compounds in the entire sample set each year it was sampled. In 2018 forty-five compounds were detected in July with a cumulative concentration of 4889 ng/L PPCPs and 103 ng/L pesticides. In August, and forty-two PPCP compounds were detected with a cumulative concentration of 10,583 ng/L and two pesticides with a cumulative concentration of 72.7 ng/L. Almost all detections were pharmaceutical compounds including psychostimulant drugs. Two pesticides (Diuron and Prometon) were also detected. Observed discharges in the outfall were low, so observed loading was also low.

In the last three sampling events, numerous compounds were observed in each sampling event suggesting that they are persistently input into the WWTP. The community of Ronan maintains a hospital facility, but it cannot be discerned what this facility contributes relative to inputs from individual homes connected to the community sewer system. Numerous compounds have been detected, including ten separate pesticides, pharmaceutical compounds and AWC's. Concentrations are generally elevated relative to other stream sampling locations.

The RWWTP will be sampling influent in 2019 to evaluate PPCPs and Pesticides to better treat the City's wastewater. Results from that study will be made available to the CSKT National Point Source Discharge Elimination System Program (NPDES).

Today, it is difficult to resolve the discrepancy in results between the up and downstream locations on Crow Creek. The upstream location does not include Mud Creek and a number of irrigation return flows. A more detailed synoptic (concurrent) sampling program would be required to understand additive contributions and concentration patterns in lower Crow Creek.

PPCPs detected in Crow Creek Below Ronan WWTP collected July 17, 2018

Sample Number	Parameter	Result	Unit	Reporting Limit	Total Load (lb)	Percent Concentration
20	10,11-dihydro-10-hydroxycarb amazepine	45.5	ng/L	10	0.0000645	0.93058453
	Acetaminophen	10.9	ng/L	10	0.0000155	0.222931239
	Bupropion	24.8	ng/L	10	0.0000352	0.5072197
	Caffeine	13.9	ng/L	10	0.0000197	0.284288461
	Carbamazepine	122	ng/L	10	0.0001729	2.495193684
	Carisoprodol	20.3	ng/L	10	0.0000288	0.415183867
	DEET	66.7	ng/L	10	0.0000946	1.364175563
	Desmethylvenlafaxine	412	ng/L	10	0.0005840	8.426391786
	Dextrorphan	60.6	ng/L	10	0.0000859	1.239415879
	Diphenhydramine	18.3	ng/L	10	0.0000259	0.374279053
	Fluconazole	84.4	ng/L	10	0.0001196	1.726183172
	Gabapentin	1850	ng/L	10	0.0026225	37.83695341
	Gemfibrozil	178	ng/L	10	0.0002523	3.64052849
	Hydrochlorothiazide	25.6	ng/L	10	0.0000363	0.523581626
	Hydroxybupropion	110	ng/L	10	0.0001559	2.249764797
	Lamotrigine	562	ng/L	10	0.0007967	11.49425287
	Lidocaine	96.8	ng/L	10	0.0001372	1.979793022
	Meprobamate	48.4	ng/L	10	0.0000686	0.989896511
	Metaxalone	104	ng/L	10	0.0001474	2.127050354
	Metformin	18.8	ng/L	10	0.0000267	0.384505256
	Methamphetamine	38.9	ng/L	10	0.0000551	0.795598642
	Metoprolol	29.5	ng/L	10	0.0000418	0.603346014
	Monoethylglycinexylidide	35.4	ng/L	10	0.0000502	0.724015217
	Norfentanyl	10.2	ng/L	10	0.0000145	0.208614554
	Norquetiapine	11.1	ng/L	10	0.0000157	0.22702172
	Oxcarbazepine	41.6	ng/L	10	0.0000590	0.850820142
	Phenobarbital	17.8	ng/L	10	0.0000252	0.364052849
	Phenytoin	125	ng/L	25	0.0001772	2.556550906
	Pregabalin	191	ng/L	10	0.0002708	3.906409784
	Primidone	18.2	ng/L	10	0.0000258	0.372233812
	Pseudoephedrine	15	ng/L	10	0.0000213	0.306786109
	Ritalinic acid	46.4	ng/L	10	0.0000658	0.948991696
	Sotalol	60.2	ng/L	10	0.0000853	1.231234916
	Sulfamethazine	11.6	ng/L	10	0.0000164	0.237247924
	Sulfamethoxazole	14.1	ng/L	10	0.0000200	0.288378942
	Temazepam	31.7	ng/L	10	0.0000449	0.64834131
	Tramadol	247	ng/L	10	0.0003501	5.05174459
	Triamterene	13.2	ng/L	10	0.0000187	0.269971776
	Valsartan	26.2	ng/L	10	0.0000371	0.53585307
	Venlafaxine	11.2	ng/L	10	0.0000159	0.229066961
	Warfarin	10.2	ng/L	10	0.0000145	0.208614554
	Zolpidem phenyl-4-carboxylic acid	10.9	ng/L	10	0.0000155	0.222931239
	Pesticides					
	Diuron	32.1	ng/L	20	0.0000455	0.656522273
	MCPP	26.4	ng/L	20	0.0000374	0.539943551
	Prometon	44.9	ng/L	20	0.0000636	0.918313085

Pesticides detected in Crow Creek below Ronan WWTP sample collected August 28, 2018

Sample Number	Parameter	Result	Unit	Reporting Limit	Total Load (lb/day)	Percent Concentration
20	10,11-dihydro-10-hydroxycarb amazepine	231	ng/L	10	0.00017680	2.182745913
	Acebutolol	10.8	ng/L	10	0.00000827	0.102050458
	Acetaminophen	20.8	ng/L	10	0.00001592	0.196541623
	Bupropion	44.8	ng/L	10	0.00003429	0.42332042
	Carbamazepine	284	ng/L	10	0.00021737	2.683549088
	Carisoprodol	51.3	ng/L	10	0.00003926	0.484739677
	DEET	130	ng/L	10	0.00009950	1.228385146
	Desmethylvenlafaxine	972	ng/L	10	0.00074395	9.184541245
	Dextrorphan	75.7	ng/L	10	0.00005794	0.71529812
	Diphenhydramine	25.8	ng/L	10	0.00001975	0.243787206
	Fluconazole	104	ng/L	10	0.00007960	0.982708117
	Gabapentin	3040	ng/L	10	0.00232676	28.72531418
	Gemfibrozil	437	ng/L	10	0.00033447	4.129263914
	Hydrochlorothiazide	53.2	ng/L	10	0.00004072	0.502692998
	Hydroxybupropion	262	ng/L	10	0.00020053	2.475668525
	Ibuprofen	41.2	ng/L	10	0.00003153	0.3893036
	Lamotrigine	1550	ng/L	10	0.00118634	14.64613059
	Lidocaine	273	ng/L	10	0.00020895	2.579608807
	Lorazepam	11.2	ng/L	10	0.00000857	0.105830105
	Meprobamate	154	ng/L	10	0.00011787	1.455163942
	Metaxalone	154	ng/L	10	0.00011787	1.455163942
	Metformin	15.7	ng/L	10	0.00001202	0.148351129
	Methamphetamine	99.6	ng/L	10	0.00007623	0.941132004
	Metoprolol	119	ng/L	10	0.00009108	1.124444864
	Monoethylglycinexylidide	112	ng/L	10	0.00008572	1.058301049
	Norfentanyl	14.6	ng/L	10	0.00001117	0.137957101
	Norquetiapine	16.1	ng/L	10	0.00001232	0.152130776
	Oxazepam	12.4	ng/L	25	0.00000949	0.117169045
	Oxcarbazepine	201	ng/L	10	0.00015384	1.899272418
	Phenobarbital	12.6	ng/L	10	0.00000964	0.119058868
	Phentermine	68.1	ng/L	10	0.00005212	0.643484834
	Phenytoin	582	ng/L	10	0.00044545	5.499385807
	Pregabalin	407	ng/L	10	0.00031151	3.845790419
	Primidone	34.2	ng/L	10	0.00002618	0.323159785
	Pseudoephedrine	22.4	ng/L	10	0.00001714	0.21166021
	Ritalinic acid	90.9	ng/L	10	0.00006957	0.858924691
	Sotalol	180	ng/L	10	0.00013777	1.700840971
	Sulfamethazine	50	ng/L	10	0.00003827	0.472455825
	Temazepam	39.2	ng/L	10	0.00003000	0.370405367
	Tramadol	454	ng/L	10	0.00034748	4.289898894
	Triamterene	10.7	ng/L	10	0.00000819	0.101105547
	Valsartan	116	ng/L	10	0.00008878	1.096097515
	Pesticides					
	Diuron	32.9	ng/L	20	0.00002518	0.310875933
	Prometon	39.8	ng/L	20	0.00003046	0.376074837

SECTION FIVE: DISCUSSION

Pesticides and contaminants of emerging concern (including PPCPs) have been widely detected in surface waters in the Columbia Basin (Morace, 2012; Columbia River Toxics Reduction Working Group, 2014), and more generally in water bodies across the globe (Gilliom and others, 2006; WHO, 2011).

While pesticides have long been observed in the water cycle and amplified in the ecosystem through bioaccumulation in aquatic and terrestrial life, the prevalent observation of CEC's in surface and ground water is a more recent phenomenon. The U.S. Geological Survey completed a national reconnaissance survey of 139 streams and observed one or more CEC's in over eighty percent of sample locations (Barnes and others, 2008). Mixtures – combinations of one or more compounds that may or may not have additive adverse environmental effects, were common in the sample sets. Observation of CEC's at very low levels (ng/l) is mainly attributable to advances in analytical methods and detection equipment. (WHO, 2011). For example, tandem mass spectrometry (LC-MS/MS), utilized by the EPA Region 8 lab, permits detections of pharmaceutical compounds at the ng/l level.

Observed detections in the Programs dataset are consistent with regional and national findings and affirmatively demonstrate that there are transport pathways for pesticides, CEC's, and waste compounds to enter Reservation surface waters. However, the presence of these compounds alone does not indicate deleterious human health and/or aquatic life influences.

Ambient water quality criteria are numeric levels of individual pollutants, or narrative descriptions of conditions in a water body that, if met, should protect designated uses. The most restrictive designated uses are generally human health, aquatic life and recreational uses. Human and aquatic life water quality criteria are developed to protect against acute effects – criterion maximum concentration, and against chronic, or longer-term exposure – criterion continuous concentration levels. Criteria are pollutant-specific, and do not address synergistic adverse effects from mixtures of pollutants.

Water quality criteria have not been developed for most CEC's, including pharmaceutical compounds.

Criteria are available for a range of pesticides and anthropogenic organic and non-organic waste compounds, and some of these may be considered CEC's.

Estrogen disrupting compounds found in surface waters have long been recognized to modify sexual development, maturation, and reproduction of aquatic life (EPA, 2008). More recent research (Shoenfuss et al., 2015) has shown that mixtures of pharmaceutical compounds can adversely affect fish species. Specifically, the authors exposed fish to nine pharmaceutical compounds - temazepam, a sleep aid; methocarbamol, a muscle relaxant; tramadol, an opioid agonist; hydrocodone, methadone, and oxycodone, opioids; and fluoxetine, paroxetine, and venlafaxine-antidepressants. The authors observed reduced growth in juvenile fish and enlarged livers in adult fish. Several of these pharmaceuticals were observed in WWTP outfalls in the Program dataset.

The CSKT Water Quality Standards (CSKT, 2018) are the applicable standards to compare observed compound concentrations to a numeric or narrative criterion. The CSKT standards associate waterbody segments with specific classifications, with A-closed being the most protective and C-3 being the least protective. The appropriate criteria for compounds analyzed in this report relates to the section on toxic or deleterious substances. With the exception of A-closed waterbodies, which do not allow for increases of toxic substances above natural levels, the criteria indicate that toxic or deleterious substances, after conventional treatment, should not exceed numeric levels found in the EPA Safe Drinking Water Act (SDWA) primary or secondary drinking water standards or the Tribal numeric criteria chart (based on SDWA levels). This standard is relaxed for waters designated as C-3 waterbodies (Hot Springs Creek below WWTP) to include only the Tribal numeric criteria chart. The SDWA and Tribal numeric charts do not include most CEC's.

The U.S. Geological Survey has developed an interactive website, updated in 2017, to provide health- based screening levels (HBSL) for 777 pollutants (https://cida.usgs.gov/hbsl/). While EPA criteria are typically reported as maximum contaminant levels (MCL's), which are enforceable standards, the HBSL's are non-enforceable water quality benchmarks that can be used as a frame of reference for

observed pollutant levels. One advantage of the HBSL database is that is includes a number of pharmaceutical and CEC compounds.

The following sections profile the top five analytes found for each of the compound classes (Table 15.0). This effort could be expanded upon to include additional analytes of interest and mixtures of compounds.

Pesticides

Pesticides are widely applied for the control of weeds, insects and other pests and have well recognized societal benefits. However, there are recognized adverse effects from pesticides, pesticide degradates, as well as mixtures of pesticides. Pesticide transport from source to receiving water is generally diffuse or nonpoint source in nature and can occur via air pathways, in solution in soil or subsoil pore water, in groundwater (saturated flow), or in solution or sorbed to sediment surfaces in surface runoff. Point source, or non-label applications such as direct application to surface waters (overspray), are thought to occur infrequently. The most common transport pathway is via overland runoff during and after hydrologic events. The highest concentrations are generally observed when hydrologic events overlap with higher application rates (Gilliom and others, 2006), for example in the May-June period in western Montana.

On the Reservation, primary surface flow pathways would be via road rights-of-way ditches and in irrigation return flows. Due to pervasive irrigation in valley floor areas, ephemeral and intermittent drainage networks are often saturated during the irrigation season, and this may increase the potential interconnection between application areas and receiving streams.

The environmental fate of pesticides is directly related to their chemical structure, and can be approximated by understanding their persistence in the environment – often reported as half-life, the behavior of degradation products, and preferential partitioning (affinity) between environmental media -water and sediment and soil. Partitioning between water and soil determines the dominant transport pathway for

a compound and is described by a soil organic carbon-water or octanol-water partition coefficient (K_{oc}). Pesticide half-life and partition coefficients can often be found in the literature and are critical to understanding pesticide mobility, persistence, and likely occurrence in aquatic settings. For example, high K_{oc} pesticides would be considered hydrophobic, would be preferentially bound to soil and organic matter, and expected to move to surface water bound to suspended sediment.

In their widely cited national survey of pesticide occurrence, USGS researchers (Gilliom and others, 2006) found one or more occurrence of pesticides or degradates in over ninety-five percent of the nation's surface water draining agricultural lands and over sixty percent of shallow groundwater. The most widely observed herbicides were related to corn production (Atrazine and metolachlor), but Prometon, 2,4-D and Diuron – herbicides found in the Program dataset, were frequently detected.

Pesticide concentrations were found to vary seasonally, with seasonal pulses associated with pesticides application timing, frequency and magnitude of rainfall or snowmelt runoff, and land management practices such as irrigation (Gilliom and others, 2006). Sampling for pesticides needs to reflect this seasonality to accurately characterize concentration and load patterns.

Mixtures of pesticides can include a wide range of formulations, with unique mixtures related to crop types and application patterns. Mixtures have been shown to have synergistic adverse effects to aquatic life (Laetz et al., 2009).

The U.S. Geological Survey reports on pesticide use by county for a range of compounds (https://water.usgs.gov/nawqa/pnsp/usage/maps/about.php). The methods applied to develop estimates are reported in Baker and Stone (2015). For Lake County, for the year 2016, the USGS report:

- 10,274 pounds of 2,4-D were applied;
- 24,749 pounds of glyphosate were applied; and

- 3,124 pounds of diuron were applied.

Values are not available for DEET or Prometon, two of the five most commonly detected pesticides in the Program dataset.

Figure 18.0 summarizes the distribution of detections for the most commonly reported pesticides; data are reported as interquartile ranges, with MCL's or HBSL's reported in ug/l where available.

2,4-D is a widely utilized broad leaf herbicide that is the active ingredient in numerous commercial herbicide formulations. 2,4-D has a half-life of one to fourteen days in soil, suggesting it is not persistent in the environment. The SDWA maximum contaminant level for 2,4-D is 70 ug/l. 2,4-D is not identified as a human carcinogen and is considered non-toxic to honey bees and slightly toxic to fish species. (http://npic.orst.edu/factsheets/24Dgen.html). Ether formulations of 2,4-D may be highly toxic to fish species, but have not been included in analytical schedules since 2008.

2,4-D and its metabolites were detected in forty-three samples, with the highest concentration reported in West Miler Coulee at 1,610 ng/l. Figure 18.0 indicates a distribution of detections on the high side of the median concentration – positive outliers. This suggests that certain of the sampling events overlapped with application events or combined application and hydrologic events. No detections approached the EPA MCL for 2,4-D.

DEET (diethyltoluamide) is a very common active ingredient in insect repellents, is widely applied, and has been observed in the nation's waters at low concentration levels for a number of years. The EPA completed an interim review update of DEET and found that it does not present a health concern to the general population or to fish and wildlife http://npic.orst.edu/factsheets/DEETgen.html. No MCL or HBSL values were found for DEET. DEET was detected twenty-four times, with a maximum concentration of 149 ng/l.

Prometon (common name Pramitol) is an herbicide that is widely used for annual and perennial broad leaf weed treatment, generally in non-crop settings. It is very commonly detected in surface and ground water, often in urban environments (Gilliom et al., 2006). Prometon is in the family of triazine pesticides

https://edis.ifas.ufl.edu/pdffiles/PI/PI15800.pdf. These are generally considered to have low toxicity to wildlife and no known effect on bees. Prometon is identified as moderately toxic to fish. No MCL is reported for Prometon, but the USGS reports a HBSL of 400 ug/l. Prometon was detected in nine samples, with a maximum concentration of 200 ng/l, well below the HBSL.

Glyphosate (Roundup) is an herbicide that is commonly applied to control annual weeds, especially grasses in cropped fields. Glyphosate preferentially partitions to soil and solid surfaces and this reduces mobility and potential transport to water. Glyphosate has a half-life ranging between two and 197 days, typical half-life values are reported at forty-seven days

(http://pmep.cce.cornell.edu/profiles/extoxnet/dienochlor-glyphosate/glyphosate-ext.html), npic.orst.edu/factsheets/archive/glyphotech.html).

Glyphosate is reported to have low to no toxicity to aquatic species, wildlife, and honey- bees. The MCL is 700 ug/l. A certain amount of controversy surrounds use of glyphosate, since several genetically modified crops have been developed that are resistant to its field application. There is little evidence at this time that glyphosate poses a threat to humans when used in typical application amounts http://npic.orst.edu/factsheets/archive/glyphotech.html.

Glyphosate was detected in nine samples with a maximum concentration of 170 ng/l. This value is well below the MCL value.

Diuron is a general use herbicide, applied in crop and non-crop settings. Diuron has a half-life ranging from 30 days to one year and is moderately to highly persistent in soils and mobile in the environment. Metabolites have lower mobility than the parent product. Diuron is considered moderately toxic to birds, moderately toxic to fish, and highly toxic to aquatic invertebrates. Diuron is non-toxic to bees http://extoxnet.orst.edu/pips/diuron.htm, https://www3.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-035505_27-Aug-01_043.pdf.

Diuron metabolites may have higher toxicity than the parent material. A MCL value is not reported for Diuron, however the USGS reports a HBSL of 20 ug/l. Eight detections of diuron and its metabolites were observed, with ninety percent of the detections occurring in West Miller Coulee and the Ronan WWTP. The highest observed concentration was 101 ng/l.

Pharmaceuticals and Personal Care Products

PPCP compounds are considered as contaminants of emerging concern despite their having been developed with the objective to provide substantial benefit to society. Pharmaceutical compounds present a unique challenge for discussion since this is an emerging area of research, there are few if any criteria or standards to benchmark to, the spiral effects of pharmaceuticals in the environment are not well understood, and the topic requires a specialized biochemistry skill set to fully grasp. PPCPs are recognized to enter the environment through WWTP outfalls, through direct disposal into waterbodies, through onsite septic systems, and to a lesser extent storm-water runoff. WWTP discharges are by far

the largest cumulative source of PPCPs (WHO, 2011).

There are a number of key resources related to the topic. Daughton and Ternes (1999) prepared a comprehensive overview and identified that PPCP's are continuously input into the environment, as a result of continuous use by humans. The effects of continuous low concentration inputs - pseudo- persistence - exposes generations of aquatic organisms to low levels of biologically active compounds. Barnes and others (2008), through a nationwide reconnaissance of 139 streams, found PPCPs in approximately eighty percent of the sample locations. The EPA (2008) developed a topic paper on Aquatic Life Criteria for CEC's. The paper focused on endocrine-disrupting compounds, including synthetic estrogens, that are capable of disrupting hormonal response in aquatic species. In 2011, the World Health Organization prepared a synthesis on Pharmaceuticals in Drinking Water. The authors documented low level, but pervasive occurrence of pharmaceutical chemicals in both surface and ground water drinking sources. McEneff and others (2014) prepared a comprehensive and technically accessible report on pharmaceutical compounds in the environment, ranging from potential

sources to treatment technologies, to effects on human and animal life. There is an extensive body of growing literature documenting the occurrence of PPCPs, their fate and transport in the environment, their effect on aquatic species, and methods to improve wastewater treatment to reduce discharges.

For the 2015 through 2017 sample period, seventy-two percent of samples exhibited detections of pharmaceutical compounds (Table 14.0). Detections were observed in treatment plant outfalls and in natural stream locations. Between thirty-five and forty-eight separate pharmaceutical compounds were detected in the Ronan WWTP. In addition to over-the-counter and prescription drugs, psychostimulant drugs, and drugs recognized as targets for opioid or other abuse behaviors were detected. The most commonly detected PPCP compounds were Gabapentin, Metformin, Caffeine, Phenobarbitol, and Diclofenic.

Gabapentin (trade name Neurontin) is an anticonvulsant used to treat seizures and neuropathic pain. It was the third most common compound identified in the overall Program dataset. Gabapentin is identified as highly water soluble, and this may partially account for its prevalence in sample results.

Gabapentin was found in nine of thirteen samples in the Little Bitterroot River and in two of twelve samples in Crow Creek near the mouth and its presence at these locations either points to continuous inputs or persistence in the environment. Concentrations of Gabapentin were high in the Ronan WWTP, ranging from 1,810 ng/l to 4,330 ng/l, and accounted for a large percentage of the total mass loading at this location. Gabapentin has been reported in several datasets in the literature, but there is little information on its environmental effects. No MCL or HBSL is available for the compound.

Metformin is a widely used diabetes medicine, commonly used for type-2 diabetes. Metformin has been widely reported in surface waters in the US, Europe, and Canada. In a recent review (Neimuth and Klaper, 2015) demonstrated that, although Metformin is dissimilar in chemical structure to endocrine- disrupting compounds, Metformin lead to intersex in male fish, reduced fecundity in fish, and a reduction in size of male fish at concentrations similar to those found in the

environment. The authors speculate that, given its persistent detection in the environment, it may be another cause of intersex fish seen across the globe. Metformin was detected in twenty samples in both WWTP outfalls and natural stream segments.

Caffeine is a mild stimulant that is both a naturally occurring compound and a synthesized compound. Caffeine is used as a consumable food product, and is generally thought of as an environmental tracer, in that it is relatively mobile in the environment and it is widely distributed. Caffeine has been widely observed in emerging contaminants datasets and was observed at a number of locations in the Program datasets.

Phenobarbital is an antiseizure medicine that is widely used for epilepsy and other forms of seizure. Phenobarbital has been reported in surface water datasets, but there is very limited information on it fate and transport, or aquatic life effects. There are no MCL's or HBSL's for phenobarbital. The compound was primarily detected in WWTP outfalls.

Diclofenac is an anti-inflammatory drug used to treat forms of arthritis and other inflammatory conditions. Diclofenac is widely reported in the environment, and there is a large body of literature indicating adverse effects to aquatic and terrestrial life (McEneff et al., 2014). Diclofenac is considered a priority pollutant by the European Union, and while not currently regulated, it is under monitoring as a candidate to add to the list of regulated pollutants. A number of studies have documented adverse effects to fish at concentration levels found in environmental samples. Diclofenac was found at low concentrations in both stream segments and WWTP outfalls.

SECTION SIX: CONCLUSIONS AND RECOMMENDATIONS

The Pesticides Program has developed a long-term dataset for pesticides, pharmaceutical and personal care products, and certain anthropogenic organic waste compounds in surface waters in several watersheds across the Reservation. In no instance did individually detected compounds approach a human health

standard or water quality criteria (MCL or HBSL). That said, many of the CEC's do not have applicable water quality criteria, and human ecological health implications are an area of active research.

The dataset does clearly demonstrate that there are transport pathways for human-derived compounds, pollutants or otherwise, to reach most surface water segments on the Reservation. The dataset also documents a concerning contribution of numerous pharmaceutical compounds in WWTP outfalls. With the exception of least-impaired headwater locations sampled in 2008, one or more compound was detected at each sample location, and at the long-term stream locations – Little Bitterroot River and Crow Creek near the mouth, compounds were detected in over ninety percent of the sample sets. This is significant for a number of reasons:

- sampling intervals are infrequent and represent snapshots of water quality conditions; exceedances, loading events, or continuous chronic inputs may not be captured in the dataset;
- growth, continued use of human-derived compounds, and greater discharges will inevitably lead to higher mass loading through time;
- many of the sampled analytes are CEC's, and limited information is available to understand human and ecological risk; and
- mixtures of compounds are recognized to have synergistic adverse effects, and these are not well understood.

Combined, these unknowns should be considered as risk uncertainties that require a more conservative management approach until data gaps are addressed.

Below, the objectives for the Program's monitoring efforts that were enumerated in Section One are examined.

1. *Document the presence or absence of pesticides, PPCP's, and other contaminants of emerging concern in various surface waters across the Reservation.* The Program has effectively maintained a sample collection project over a ten-year span to document the presence or absence of target analytes. There are several additional aspects that would improve the characterization of potential contaminants, but the effort was driven by limited available resources.
2. *Document concentration levels and benchmark these to human health and/or ecological criteria, where available.* Water quality criteria are not

available for most CEC's, but where they are available, data indicate that observed concentrations were well below applicable criteria or benchmark's.

3. *Sample WWTP outfalls, based on prior-year detections of CEC's in natural streams downstream of treatment outfalls*. This objective was effectively completed, but it should be considered as an entry point into this topic with a number of outstanding questions.
4. *Continue the year-to-year dataset to look for patterns at and between locations*. This objective was met, but with the infrequent sample schedule it is difficult to reach conclusions related to seasonality in compound concentrations or patterns between locations.
5. *Provide a quality-assured dataset that may be used for pesticides and water quality management.* Quality assurance was documented for each sampling event, and allows users to understand the limitations within each sample set.

Several specific technical recommendations are set out below. These recommendations are provided considering the longevity of the sampling project, and the potential to move the project in new directions.

1. The Quality Assurance Project Plan should be re-evaluated given the extremely low detection levels achieved by the analytical lab. The criteria to evaluate quality control may not be directly applicable to data reported at the ng/l level. Program staff should place more emphasis on total quality control to reduce the amount of estimated data qualifiers. **For example, quality control samples should be collected at locations other than the Little Bitterroot River to reduce potential bias in the results**. Samples should also be delivered to the lab in suitable condition and sample labeling and location documentation should be more transparent to the user. These recommendations may be best addressed by clearly designating and assigning responsibility to a quality control staff person.
2. The Program should consider a complete re-evaluation of their sampling activities and document this through a sampling and analysis plan. The Program may want to start this process by asking a set of questions.
    a. Does the Program need to continue ambient pesticides monitoring at several locations, or should we target two to four locations?
    b. Should the Program try to sample a subset of locations more frequently to try to capture seasonal use and the distribution of outlier data?
    c. Can the Program sample pesticides in May or June when flows are higher and we are sampling closer to the application time periods?
    d. Should the Program tie certain analytical schedules to specific sample locations; i.e. Should we sample for pharmaceuticals in agricultural

Commented [A2]: This is key. I would recommend that sampling move up to Spring if possible and refine your sampling locations. The number of no detections in the 2018 sample round is likely due to the August time period.

areas? Should we restart AWC monitoring in Ronan Spring Creek, and potentially other water bodies? Should we try to expand the pharmaceutical monitoring to other WWTP outfalls?

e. Should the Program expand the project to include shallow groundwater or drinking water sources?
f. Should the Program expand the project to include streambed and wetland sediments, matrices where hydrophobic compounds may reside in a stream network?

Commented [A3]:

The above points are posed as questions to use as a starting point to re-examine the objectives for the sampling program.

3. Given the high number of detections in WWTP outfalls, the Program should consider more in- depth work to understand the attenuation of compounds in the receiving streams. This work could initiate in Crow Creek, where there are number of outstanding questions, such as, "how do pharmaceutical compounds persist downstream to the mouth of the drainage?"
4. The Program should consider further mining the existing data and literature to understand the influence of mixtures of compounds and potential human health and ecological risk from mixtures of compounds.

In conclusion, the Pesticides Program has developed a well-documented dataset for pesticides, pharmaceuticals and personal care products, and certain anthropogenic organic waste compounds. The value of a dataset of this type grows over time, as it provides a baseline or reference to measure future conditions against. Recognizing that the project has achieved a ten-year milestone, Program staff should take this opportunity to adapt the project to address finding in the data and emerging information in the field.

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Commented [A4]:

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Appointment

From: Federoff, Nicholas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=979D66A50E374DC981E7BBA7E805F0C5-NICHOLAS E. FEDEROFF]
Sent: 6/15/2020 11:22:44 AM
To: Rate, Debra [Rate.Debra@epa.gov]

Subject: Accepted: Team Meeting - Aldicarb new uses
Location: Microsoft Teams Meeting

Start: 6/15/2020 12:30:00 PM
End: 6/15/2020 1:00:00 PM
Show Time As: Busy

Appointment

From: Federoff, Nicholas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=979D66A50E374DC981E7BBA7E805F0C5-NICHOLAS E. FEDEROFF]
Sent: 11/20/2019 12:24:30 PM
To: Rate, Debra [Rate.Debra@epa.gov]

Subject: Declined: Aldicarb - nPCT and dietary assessment
Location: DCRoomPYS7671C/Potomac-Yard-One

Start: 11/20/2019 7:00:00 PM
End: 11/20/2019 7:30:00 PM

Recurrence: (none)

Message

From: Arnold, Elyssa [Arnold.Elyssa@epa.gov]
Sent: 10/29/2019 12:24:19 PM
To: Federoff, Nicholas [Federoff.Nicholas@epa.gov]
Subject: RE: Aldicarb

Ex. 5 Deliberative Process (DP)

From: Federoff, Nicholas <Federoff.Nicholas@epa.gov>
Sent: Tuesday, October 29, 2019 7:58 AM
To: Arnold, Elyssa <Arnold.Elyssa@epa.gov>
Subject: Aldicarb

Ex. 5 Deliberative Process (DP)

Message

From: Ex. 6 Personal Privacy (PP) yahoo.com]
Sent: 6/18/2020 12:00:36 PM
To: Federoff, Nicholas [Federoff.Nicholas@epa.gov]
Subject: Fw: Aldicarb
Attachments: 098301_424563_PRA_10-06-15.docx; 098301 D344325 ADDENDUM EFED Risk Results RED.doc; 098301_435243_RTC_12-21-16.pdf; 098301_424563_PRA_09-11-15.docx; Honeybee toxicity.docx

----- Forwarded Message -----
Ex. 6 Personal Privacy (PP) yahoo.com>
To: "federoff.nichols@epa.gov" <federoff.nichols@epa.gov>
Sent: Thursday, June 18, 2020, 07:47:56 AM EDT
Subject: Aldicarb

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

PC Code: 098301
DP barcode: D344325

MEMORANDUM September 14, 2007

Subject: ADDENDUM to: Aldicarb - Ecological risk results for alternative application rate and incorporation efficiencies

To: Robert McNally, Branch Chief
Anne Overstreet, Team Leader
Special Review Branch
Special Review and Reregistration Division

From: Dana Spatz, Chief (acting)
Environmental Risk Branch II
Environmental Fate and Effects Division

In response to your request, the following addendum gives the risk quotients for birds and mammals exposed to aldicarb applied at maximum application rates and 99 percent granule incorporation efficiency. This analysis will help to characterize the aldicarb ecological risk assessment. Note that the risk quotients for aquatic species for this scenario were previously provided in a memo to you dated August 25, 2006 (D331981).

Table 1. Aldicarb: Acute avian RQs for 99 percent incorporation efficiency at **maximum application rates**

Crop Scenario	Bird Type	Rate (lbs ai/A)	RQ (99% incorporated)
Citrus Broadcast	Small Bird Medium Bird Large Bird	4.95	51.7 8.1 0.57
Cotton Banded/Sidedress 4" band width 40" row spacing	Small Bird Medium Bird Large Bird	4.05	428.5 67.3 4.8
Dry Beans Banded 6" band width 48" row spacing	Small Bird Medium Bird Large Bird	2.1	175.5 27.6 1.9
Sorghum Banded 2" band width 36" row spacing	Small Bird Medium Bird Large Bird	1.05	192.6 30.3 2.1
Peanuts Banded 6" band width 36" row spacing	Small Bird Medium Bird Large Bird	3.0	188.1 29.5 2.1
Pecans Broadcast	Small Bird Medium Bird Large Bird	10.05	104.9 16.5 1.2
Potatoes Banded 6" band width 38" row spacing	Small Bird Medium Bird Large Bird	3.0	198.5 31.2 2.2
Soybeans Banded 6" band width 30" row spacing	Small Bird Medium Bird Large Bird	3.0	156.7 24.5 1.7
Sugar Beets Banded 6" band width 22" row spacing	Small Bird Medium Bird Large Bird	4.95	189.6 29.8 2.1
Sweet Potatoes Banded 12" band width 48" row spacing	Small Bird Medium Bird Large Bird	3.0	124.8 19.6 1.4
Ornamentals Broadcast	Small Bird Medium Bird Large Bird	5.0	52.2 8.2 0.58

Mallard duck LD_{50} = 1 mg/kg- bw
Rat LD_{50} = 0.9 mg/kg-bw

Table 2. Aldicarb: Acute mammalian RQs for 99 percent incorporation efficiency at **maximum application rates**

Crop Scenario	**Mammal Type**	**Rate (lbs ai/A)**	**RQ (99% incorporated)**
Citrus Broadcast	Small Bird Medium Bird Large Bird	4.95	17.5 9.2 0.75
Cotton Banded/Sidedress 4" band width 40" row spacing	Small Bird Medium Bird Large Bird	4.05	144.8 76.7 6.2
Dry Beans Banded 6" band width 48" row spacing	Small Bird Medium Bird Large Bird	2.1	59.3 31.4 2.5
Sorghum Banded 2" band width 36" row spacing	Small Bird Medium Bird Large Bird	1.05	65.1 34.5 2.8
Peanuts Banded 6" band width 36" row spacing	Small Bird Medium Bird Large Bird	3.0	63.5 33.7 2.7
Pecans Broadcast	Small Bird Medium Bird Large Bird	10.05	35.4 18.8 1.5
Potatoes Banded 6" band width 38" row spacing	Small Bird Medium Bird Large Bird	3.0	67 35.5 2.9
Soybeans Banded 6" band width 30" row spacing	Small Bird Medium Bird Large Bird	3.0	53 28 2.3
Sugar Beets Banded 6" band width 22" row spacing	Small Bird Medium Bird Large Bird	4.95	64 33.9 2.7
Sweet Potatoes Banded 12" band width 48" row spacing	Small Bird Medium Bird Large Bird	3.0	42.1 22.3 1.8
Ornamentals Broadcast	Small Bird Medium Bird Large Bird	5.0	17.6 9.3 0.76

Mallard duck LD_{50} = 1 mg/kg- bw
Rat LD_{50} = 0.9 mg/kg-bw

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 21, 2016

PC Code: 098301
DP Barcode: 435243

MEMORANDUM

SUBJECT: **Aldicarb:** Response to Comments Regarding the Preliminary Ecological Risk Assessment for the Registration Review of Aldicarb

FROM: N.E. Federoff, Wildlife Biologist
James Lin, Environmental Engineer
Environmental Risk Branch 2
Environmental Fate and Effects Division (7507P)

THRU: Brian Anderson, Chief
Elyssa Arnold, Risk Assessment Process Leader
R. David Jones, Senior Agronomist
Environmental Risk Branch 2
Environmental Fate and Effects Division (7507P)

Elyssa Arnold Digitally signed by Arnold, Elyssa Date: 2016.12.22 08:17:44 -05'00'
R David Jones 2016.12.27 10:49:16 -05'00'

TO: Susan Bartow, Chemical Review Manager
Tom Myers, Team Leader
Kevin Costello, Branch Chief
Risk Management and Implementation Branch 4
Pesticide Re-evaluation Division (7508P)

The Environmental Fate and Effects Division (EFED) has reviewed the submitted comments regarding the Preliminary Risk Assessment conducted as part of the registration review of aldicarb (EPA Docket No. EPA-HQ-OPP-2012-0161). The pertinent submitted comments and EFED's responses are listed below.

1. Comments from Cotton Grower Groups

Georgia Cotton Commission, Comment EPA-HQ-OPP-2012-0161-0077

The Environmental Fate and Effects Division (EFED) report suggests modeling concerns for potential risks to birds and mammals. The NCC respectfully notes that the EFED report acknowledges no reports of incidents when aldicarb was used in compliance with label instructions. EFED acknowledged uncertainty due to their understanding of the depth of soil cover after application (Page 2, Table under Label Clarification). The NCC urges EFED to understand it is not easy to label the depth of soil cover due to multiple agronomic variables that dictate seed placement in the soil. Seed placement in the soil will vary by plant species as well as by soil type, soil moisture, rain forecast, and irrigation capabilities within a plant species. However, the placement of the aldicarb with the seed in the seed furrow covered with soil enhances compliance because of desired protection of the seed. The NCC encourages EFED to recognize the historical use that has demonstrated the lack of real risk to birds and mammals when aldicarb is used as label instruction prescribe.

The NCC urges EPA to recognize the use of aldicarb at planting offers little opportunity for impact on honey bee colonies. It is difficult to understand, from a biological and scientific perspective, why EPA would predict a risk to honey bees from an in-furrow application at planting. Although cotton flower development depends greatly on temperature and time (degree days), it typically takes more than 40 days from planting to flower development. The biological efficacy of aldicarb applied in the soil at planting does not persist for this duration of time. Additionally, studies previously provided to EPA have demonstrated that honey bees are not attracted to cotton pollen. Similarly, studies have shown little nectar production in pre-flowering cotton. EPA is urged to refine this risk assessment to reflect these biological data.

CA Cotton Ginners and Growers Associations (CCGGA), Comment EPA-HQ-OPP-2012-0161-0080

CCGGA asks that the EPA recognize that given the minimal risk, worker exposure and benefits of aldicarb and the critical void that has been created since its lack of availability, current alternatives on the market would result in multiple applications to achieve equivalent levels of protection that aldicarb provides. Additionally, our Associations asks that EPA recognize the lack of impact aldicarb in-furrow applications has on honey bee colonies. Given the environment, temperature, time (degree days) and other factors, cotton flower development typically takes more than 40 days. The efficacy of aldicarb applied in the soil at planting does not persist for this duration of time. Additionally, EPA has been provided studies demonstrating that not only are honey bees not attracted to cotton pollen but also that little nectar production in pre-flowering cotton. We would urge EPA to refine the risk assessment to reflect this biological data.

Plains Cotton Growers, Inc., Comment EPA-HQ-OPP-2012-0161-0082

Among the information reviewed was a report from the Environmental Fate and Effects Division (EFED) that suggests concerns for potential risks to birds and mammals. Despite the fact that the EFED report included no reports of harmful incidents when aldicarb is used in compliance with label instructions to support their concern, the authors did acknowledge uncertainty related to their understanding of the depth of soil cover after application. Seed placement in the soil will vary by plant species as well as by soil type, soil moisture, rain forecast, and irrigation capabilities. However, the placement of aldicarb in the seed furrow that is mechanically covered with soil minimizes the potential for exposure to non-target organisms. PCG encourages EFED to recognize the historical use data that demonstrates the lack of real risk to birds and mammals when aldicarb is used according to the current label. PCG also encourages the EPA to also recognize that use of aldicarb at planting offers little opportunity for impact on honey bee colonies. EPA is urged also to refine its risk assessment of aldicarb in regard to honey bees to reflect biological data from studies that show cotton exhibits little nectar production pre-flowering and that honey bees are not strongly attracted to cotton pollen; that flower development in cotton typically takes 40 or more days; and that the biological efficacy of aldicarb applied at planting does not persist for that length of time. Based on the available data, it is clear that aldicarb poses a minimal risk to honey bees and other species and continues to meet the standards for registration under FIFRA when used according to current label instructions. Aldicarb continues to provide cotton producers a safe and effective alternative for control of early season insect and nematode pests and we look forward to its continued availability.

National Cotton Council, Comment EPA-HQ-OPP-2012-0161-0086

The Environmental Fate and Effects Division (EFED) report suggests modeling concerns for potential risks to birds and mammals. The NCC respectfully notes that the EFED report acknowledges no reports of incidents when aldicarb was used in compliance with label instructions. EFED acknowledged uncertainty due to their understanding of the depth of soil cover after application (Page 2, Table under Label Clarification). The NCC urges EFED to understand it is not easy to label the depth of soil cover due to multiple agronomic variables that dictate seed placement in the soil. Seed placement in the soil will vary by plant species as well as by soil type, soil moisture, rain forecast, and irrigation capabilities within a plant species. However, the placement of the aldicarb with the seed in the seed furrow covered with soil enhances compliance because of desired protection of the seed. The NCC encourages EFED to recognize the historical use that has demonstrated the lack of real risk to birds and mammals when aldicarb is used as label instruction prescribe.

The NCC urges EPA to recognize the use of aldicarb at planting offers little opportunity for impact on honey bee colonies. It is difficult to understand, from a biological and scientific perspective, why EPA would predict a risk to honey bees from an in-furrow application at planting. Although cotton flower development depends greatly on temperature and time (degree days), it typically takes more than 40 days from planting to flower development. The biological efficacy of aldicarb applied in the soil at planting does not persist for this duration of time. Additionally, studies previously provided to EPA have demonstrated that honey bees are not attracted to cotton pollen. Similarly, studies have shown little nectar production in pre-flowering cotton. EPA is urged to refine this risk assessment to reflect these biological data.

EFED Responses to Comments from the Cotton Grower Groups

Risks to Pollinators

Aldicarb is considered highly toxic by acute contact exposure to honeybees with an LD_{50} of 0.285 µg/bee. Because of its granular formulation, it is unlikely that there is a direct contact exposure scenario for honeybees. However, other soil dwelling beneficial insects and invertebrates could be exposed to aldicarb and aldicarb residues through contact with the granules. Contact with dissolved residues in puddles and/or with plants (via pollen and nectar) due to its systemic nature is possible. Cotton is attractive to honey bees, bumble bees, and solitary bees under certain conditions (http://www.ree.usda.gov/ree/news/Attractiveness_of_Agriculture_crops_to_pollinating_bees_Report-FINAL.pdf). Under the Tiered approach for pollinator risk assessment, residue studies are among the type of data requested. Therefore, theoretical presumptions regarding residue levels may be tested.

Risks to Birds and Mammals

The over-riding concern for aldicarb is the high risk of mortality to birds and mammals. Aldicarb is very highly toxic to avian and mammalian species. It is a systemic pesticide and a potent cholinesterase (ChE) inhibitor. Acute and chronic RQs for aldicarb can be misleading since it can take the ingestion of only 1 granule for mortality to occur (Balcomb *et al.*, 1984). Supplemental open literature suggests acute oral LD_{50}s of 0.75 mg/kg for passerine species. The mammalian LD_{50} is similar to birds at 0.9 mg/kg. Exposure to aldicarb caused lower survivability and pup weights in offspring of all litters in testing (reproductive LOAEL = 1.4 - 1.7 mg/kg-bw; NOAEL = 0.7 - 0.9 mg/kg-bw). These toxicity values suggest that even if mammals survive acute aldicarb exposure they may suffer adverse reproductive effects from chronic exposure. In addition, since there are risks to birds, risks to reptiles are also possible.

Regarding incorporation, EFED modeled variable incorporation depths and still had risk to terrestrial organisms. Assumptions of incorporation efficiency did not reduce the level of risk to avian and mammalian species below the Level of Concern (LOC). EFED modeled 99% (for banded/sidedress), 99.5% (banded/sidedress and in-furrow) and 99.9% (banded/sidedress and in-furrow) incorporation efficiency at EPA typical application rates to investigate whether such assumptions, albeit unrealistic, would reduce the risk to below LOC for terrestrial wildlife. None of the modeling scenarios decreased the avian or the mammalian risk beyond Agency levels of concern for any of the crops. It is assumed that some amount of granules (even just one) may remain on the surface and that consumption of even a small number of granules may produce mortality.

Incidents

There have been numerous mortality incidents to birds and mammals where aldicarb was determined to be a likely cause. Even though most of the reported incidents were either from the intentional or accidental misuse of aldicarb, very few incidents that occur are reported to the EPA. The number of documented kills is believed to be a small fraction of total mortality caused by pesticides. Mortality incidents must be seen, reported, and have reports submitted to EPA to have the potential for entry into the database. Incidents often are not seen, due to scavenger removal of carcasses, decay in the field, or simply because carcasses may be

hard to see on many sites and/or few people are systematically looking. Poisoned animals may also move off-site to less conspicuous areas before dying. Incidents may not get reported to appropriate authorities capable of investigating the incident for a variety of reasons including the finder may not know of the importance of reporting incidents, may not know who to call, may not feel they have the time or desire to call, or may hesitate to call because of their own involvement in the kill. Incidents reported may not get investigated if resources are limited or may not get investigated thoroughly, with residue analyses, for example. Also, if kills are not reported and investigated promptly, there will be little chance of documenting the cause, since tissues and residues may deteriorate quickly. Reports of investigated incidents often do not get submitted to EPA, since reporting by states is voluntary.

2. **Comments from USDA, Comment EPA-HQ-OPP-2012-0161-0081**

Aquatic Exposure
EPA's model results for aquatic exposure are based on Minnesota. However, per the AgLogic 150 label, aldicarb may NOT be applied in Minnesota.

Drinking Water Exposure
Per "Table 1. Screening-Level TTR EDWCs for Proposed Uses of Aldicarb," EPA's surface water source drinking water results for drinking water were derived for sugar beets in Minnesota. However, per the AgLogic 15 G label, aldicarb label may not be applied in Minnesota. USDA seeks a refined assessment more appropriate to the existing label.

Surface Water Refinement
EPA has assumed 100% PCA. Aldicarb began to be marketed as recently as 2016 so the PCA should be refined. The Extension Service was unable to estimate the magnitude of aldicarb adoption for 2016. USDA is available to assist EPA later in this regard. USDA hopes that EPA will be able to refine the assessment using confidential sales information from the registrant. USDA requests the risk numbers be more refined using the Pesticide in Water Calculator (PWC) model instead of the SWCC.

Drinking Water Refinement
USDA believes the surface water values will be much improved when the depth of the furrows are taken into account and also the inches of soil used to cover aldicarb granules by the applicator (to be clarified by the registrant) in furrows and for side-dressings and also if Minnesota were not used as the representative site. Moreover, there are numerous states where aldicarb cannot be applied. Also, the label provides directions for on appropriate actions in areas of vulnerable soils whereas the EPA PRZM-GW assumes "high leaching potential soils."

It appears that Minnesota was used as the basis for the ground water assessment. USDA seeks that the modeling be based on where aldicarb is currently labeled. This would accurately reflect the application time, meteorology, soil types, soil temperatures and pH of where aldicarb is used. EPA's refined assessment should also take into consideration the soil restrictions noted on the label for each listed state beginning on Page 17 of the AgLogic 15G label. USDA notes the label restrictions regarding vulnerable soils to protect groundwater which may be used for drinking water such as: "If AgLogic 15G is applied to cotton as an At-Plant application and a Side Dress application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within l000 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 1000 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface."

EFED Responses to USDA Comments

Aquatic Exposure and Drinking Water Exposure:
The Minnesota sugar beets scenario is a surrogate for Minnesota and other areas with similar soils and weather patterns and is not limited to represent only Minnesota.

Surface Water Refinement
The PCA factor is based on EFED's most recent guidance document, which indicates that for All-Ag uses, the value of 1.0 should be used. The guidance "Development of Community Water System Drinking Water Intake Percent Cropped Area Adjustment Factors for use in Drinking Water Exposure Assessments: 2014 Update" is available at: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/development-community-water-system-drinking-water.

Drinking Water Refinement
Typical in-furrow applications are made across the open furrow and not placed at the bottom of the furrow. This causes the granules to be spread through the depth of the furrow when the furrow is closed. This is reflected using CAM = 4 option in PRZM, or the 'uniform' option in PWC. While placing the pesticide at the bottom of the furrow (CAM = 8, or @depth) is possible, it would not be the typical practice unless specific instructions to do so were included on the label. The label modification is required for the farmer to change the nozzle used to release the pesticide, or at least adjust its depth to affect application at the bottom of the furrow to make sure all granules are dropped below the runoff extraction zone. Also with granule applications, dusting-off can be commonly observed and the label also needs to address this aspect.

The ground water estimated concentrations were based on the Florida Central Ridge scenario, which provides the highest concentrations among the six available ground water scenarios. Modeling with the new PWC version 1.52, the ground water concentrations at pH 6, 7, and 8 are presented below:

Modeled Scenario	Ground-water pH	Max. Daily Conc. (µg/L)	Mean Breakthrough Time (yrs)	Post-breakthrough Mean (µg/L)
FL Central Ridge	6	100	3.4	31
	7	33		3.5
	8	1.25		0.002

The differences of the concentrations are due to the influence of the hydrolysis half-life. The half-life values are 152 days, 63 days, and 6 days for pH at 6, 7, and 8, respectively.

To account for the well setback distances, EFED used a plug flow model to simulate the additional travel time for a pesticide to reach a drinking water well from point of application, which is explained in the drinking water assessment. The reduction factor is based on a typical high-end lateral ground water velocity of 1 ft/day as recommended in the PRZM-GW guidance document[1]. A slower flow of 0.1 ft/day is also explored here.

[1] USEPA. 2012. Guidance for Selecting Input Parameters for Modeling Pesticide Concentrations in Groundwater Using the Pesticide Root Zone Model. Version 1.0. U.S. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division; Health Canada, Pesticide Management Regulatory Agency, Environmental Assessment Directorate. Oct. 15, 2012.

At pH 6, the k value (degradation rate in aquifer) is 0.00456/day based on the hydrolysis half-life of 152 days. The effects of well setback at different distances are as follows:

Well Setback (ft)	1 ft/day Ground-water Velocity		0.1 ft/day Ground-water Velocity	
	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)
50	79.61	24.68	10.23	3.17
300	25.46	7.89	1.14E-4	3.55E-5
500	10.23	3.17	1.25E-8	3.88E-9
700	4.11	1.27	Not calculated	Not calculated
1000	1.05	0.32	Not calculated	Not calculated

At pH 7, the k value is 0.011/day based on the hydrolysis half-life of 63 days. The effects of well setback at different distances are as follows:

Well Setback (ft)	1 ft/day Ground-water Velocity		0.1 ft/day Ground-water Velocity	
	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)
50	19.04	2.02	0.134	0.0142
300	1.22	0.13	1.53E-13	1.62E-14
500	0.13	0.014	Not calculated	Not calculated
700	1.5E-2	1.5E-3	Not calculated	Not calculated
1000	5.5E-4	5.8E-5	Not calculated	Not calculated

At pH 8, the k value is 0.1155/day based on the hydrolysis half-life of 6 days. The effects of well setback at different distances are as follows:

Well Setback (ft)	1 ft/day Ground-water Velocity		0.1 ft/day Ground-water Velocity	
	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)
50	3.9E-3	6.2E-6	1.03E-25	1.64E-28
300	1.1E-11	1.8E-18	Not calculated	Not calculated
500	1.0E-25	1.6E-28	Not calculated	Not calculated
700	9.5E-36	1.5E-38	Not calculated	Not calculated
1000	8.4E-51	1.3E-53	Not calculated	Not calculated

3. **Comments from AgLogic Chemical LLC, Comment EPA-HQ-OPP-2012-0161-0083**

MRID 49956504 - Ritter, A. (2016). Aldicarb: Drinking Water Exposure Assessment for Preliminary Risk Assessment – AgLogic Comments, Rebuttal and Revised Modeling.
Considering the application methods currently on the label there should be no contaminated granules available to contribute to exposure via surface water puddles should they form. AgLogic believes that the current AgLogic 15G label application methods pose minimal risk to Nontarget aquatic and terrestrial wildlife due to current cultural practices and disagrees with EPA's conservative conclusions. Despite this, AgLogic is willing to consider potential label modifications to remove the T-band and peanut foliar applications, leaving only the in-furrow application method on the label. With the in-furrow application method, the granular formulation is incorporated at planting, at depth along with the crop seeds, and immediately covered up to a minimum of 1-inch below the soil surface. This meets the aquatic modeling requirement for no potential for aquatic exposure with incorporation of the granule a minimum of 2 cm below the soil surface (i.e., 100% incorporation), consistent with the assumption the Agency made relative to sweet potatoes in the aquatic

assessment. Thus the EECs for all labeled uses are 0 (i.e., no exposure). With no exposure from the in-furrow application method (i.e., EECs of 0), the worst case RQs for all crops would be 0, indicating negligible risk to aquatic and terrestrial organisms.

MRID 49956506 - Hancock, G (2016). AgLogic Response to USEPA Preliminary Ecological Risk Assessment in Support of the Registration Review of Aldicarb

The overall conclusion of this response to the risk assessment is that the weight of evidence based on over 45 years of aldicarb use in the US, the near lack of incident data attributed to label use of aldicarb, highly refined agricultural practices and equipment, the way growers use aldicarb, and state-of-the-art probabilistic aquatic and terrestrial risk assessments that concluded minimal probability of risk, convincingly refute to presumption of risk that has followed all the USEPA ecological screening level risk assessments triggered by the various regulatory actions.

EFED Response to AgLogic Comments on Water Modeling

The exposure to the granular applications is influenced by the locations of the granules (*i.e.*, the placements of the granules), EFED agrees that the registrant's mitigation proposal will reduce the potential exposure by making sure all granules are covered with soil and by removing the foliar peanut applications.

The registrant indicates that the granules are dropped in-furrow immediately before or after the seed drop. A typical in-furrow application is made across the open furrow and not placed at the bottom of the furrow. This causes the granules to be spread through the depth of the furrow when the furrow is closed. This is reflected using CAM = 4 option in PRZM, or the 'uniform' option in PWC. While placing the pesticide at the bottom of the furrow (CAM = 8, or @depth) is possible, it would not be the typical practice unless specific instructions to do so were included on the label. The label modification is required for the farmer to change the nozzle used to release the pesticide, or at least adjust its depth to affect application at the bottom of the furrow to make sure all granules are dropped below the runoff extraction zone.

EFED Response to AgLogic Comments on Ecological Assessment

There have been numerous mortality incidents to birds and mammals where aldicarb was determined to be a likely cause. Even though most of the reported incidents were either from the intentional or accidental misuse of aldicarb, very few incidents that occur are reported to the EPA. The number of documented kills is believed to be a small fraction of total mortality caused by pesticides. Mortality incidents must be seen, reported, and have reports submitted to EPA to have the potential for entry into the database. Incidents often are not seen, due to scavenger removal of carcasses, decay in the field, or simply because carcasses may be hard to see on many sites and/or few people are systematically looking. Poisoned animals may also move off-site to less conspicuous areas before dying. Incidents may not get reported to appropriate authorities capable of investigating the incident for a variety of reasons including the finder may not know of the importance of reporting incidents, may not know who to call, may not feel they have the time or desire to call, or may hesitate to call because of their own involvement in the kill. Incidents reported may not get investigated if resources are limited or may not get investigated thoroughly, with residue analyses, for example. Also, if kills are not reported and investigated promptly, there will be little chance of documenting the cause, since tissues and residues may deteriorate quickly. Reports of investigated incidents often do not get submitted to EPA, since reporting by states is voluntary.

Regarding incorporation, EFED modeled variable incorporation depths and still had risk to terrestrial organisms. Assumptions of incorporation efficiency did not reduce the level of risk to avian and mammalian species below the Level of Concern (LOC). EFED modeled 99% (for banded/sidedress), 99.5% (banded/sidedress and in-furrow) and 99.9% (banded/sidedress and in-furrow) incorporation efficiency at EPA typical application rates to investigate whether such assumptions, albeit unrealistic, would reduce the risk to below LOC for terrestrial wildlife. None of the modeling scenarios decreased the avian or the mammalian risk beyond Agency levels of concern for any of the crops. It is assumed that some amount of granules may remain on the surface and that consumption of even a small number of granules (even just one) may produce mortality.

Regarding the submitted probabilistic aquatic and terrestrial assessments, EFED conducts its assessments with current Agency approved methods. These assessments do not currently use probabilistic methods of risk assessment.

4. Comments from Earthjustice, Comment EPA-HQ-OPP-2012-0161-0087

Earthjustice suggests that the EPA prevent contamination of drinking water by aldicarb. Action is long overdue. Suggests agency moves quickly to ban these toxic pesticides now.

EFED Response to Comments from Earthjustice

The purpose of this registration review is to review all available information with the consideration of any possible mitigations. EFED will consider the risk analyses and provide its recommendations.

Appointment

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/15/2020 11:17:24 AM
To: Rate, Debra [Rate.Debra@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Blankinship, Amy [Blankinship.Amy@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]; Donovan, William [donovan.william@epa.gov]; Costello, Kevin [Costello.Kevin@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Becker, Jonathan [Becker.Jonathan@epa.gov]; Lin, James [lin.james@epa.gov]; Wente, Stephen [Wente.Stephen@epa.gov]; Gsell, Alyssa [Gsell.Alyssa@epa.gov]; Waterworth, Rebeccah [Waterworth.Rebeccah@epa.gov]
CC: Federoff, Nicholas [Federoff.Nicholas@epa.gov]

Subject: Team Meeting - Aldicarb new uses
Attachments: Draft Aldicarb Briefing Slides 061420 V2.pptx
Location: Microsoft Teams Meeting

Start: 6/15/2020 12:30:00 PM
End: 6/15/2020 1:00:00 PM
Show Time As: Busy

Required Attendees: Johnson, Marion; Adeeb, Shanta; Blankinship, Amy; Metzger, Michael; Donovan, William; Costello, Kevin; Suarez, Mark; Waterworth, Rebeccah; Hansel, Jeana; Hendrick, Lindsey; Kaul, Monisha; Becker, Jonathan; Lin, James; Wente, Stephen; Gsell, Alyssa
Optional Attendees: Federoff, Nicholas

Hi All,

Below is a brief agenda to get our discussion started this morning.

Thanks.
Debra

Agenda:

1. Proposed Timetable to Decision (PRIA date 7/15/2020):

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

3. Any remaining items/assessments?
4. Slide Deck- Bones are there, but please feel free to edit/revise slides pertaining to your division.
5. Is another team meeting needed?

Ex. 5 Deliberative Process (DP)

I only found a free ½ hour for the team, but I am prepared to schedule a follow up meeting to continue the discussion as may be needed.

Thanks in advance for your time!!
Debra

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